

Fig 1A

Gamma
Irradiation of Liquid IGIV in the Absence or Presence of
Ascorbate Alone or in Addition to Gly-Gly

Liquid IGIV, Reduced 5-15%

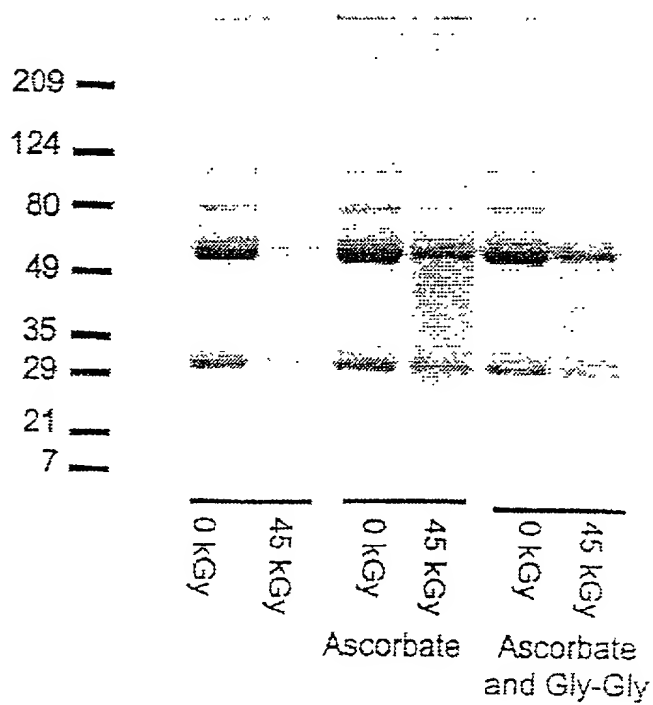


Fig 1B

Gamma Irradiation of Liquid IGIV in the Absence or Presence of Ascorbate Alone or in Addition to Gly-Gly

Liquid IGIV, Non-Reduced 5-15%

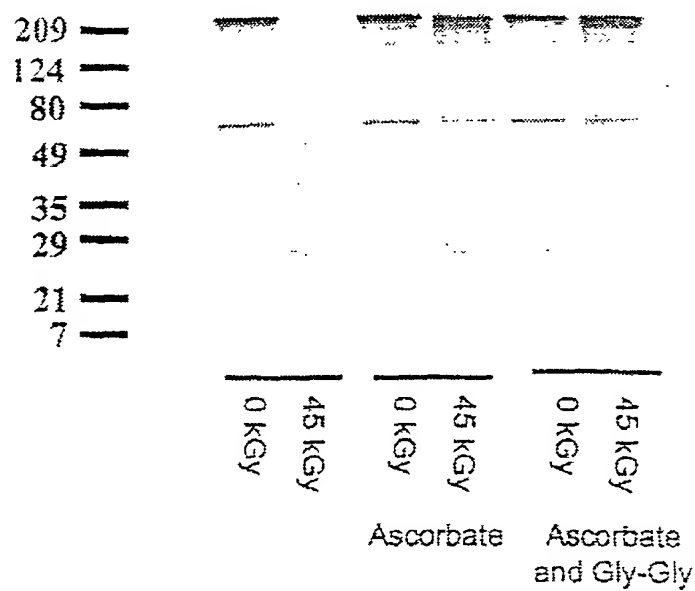
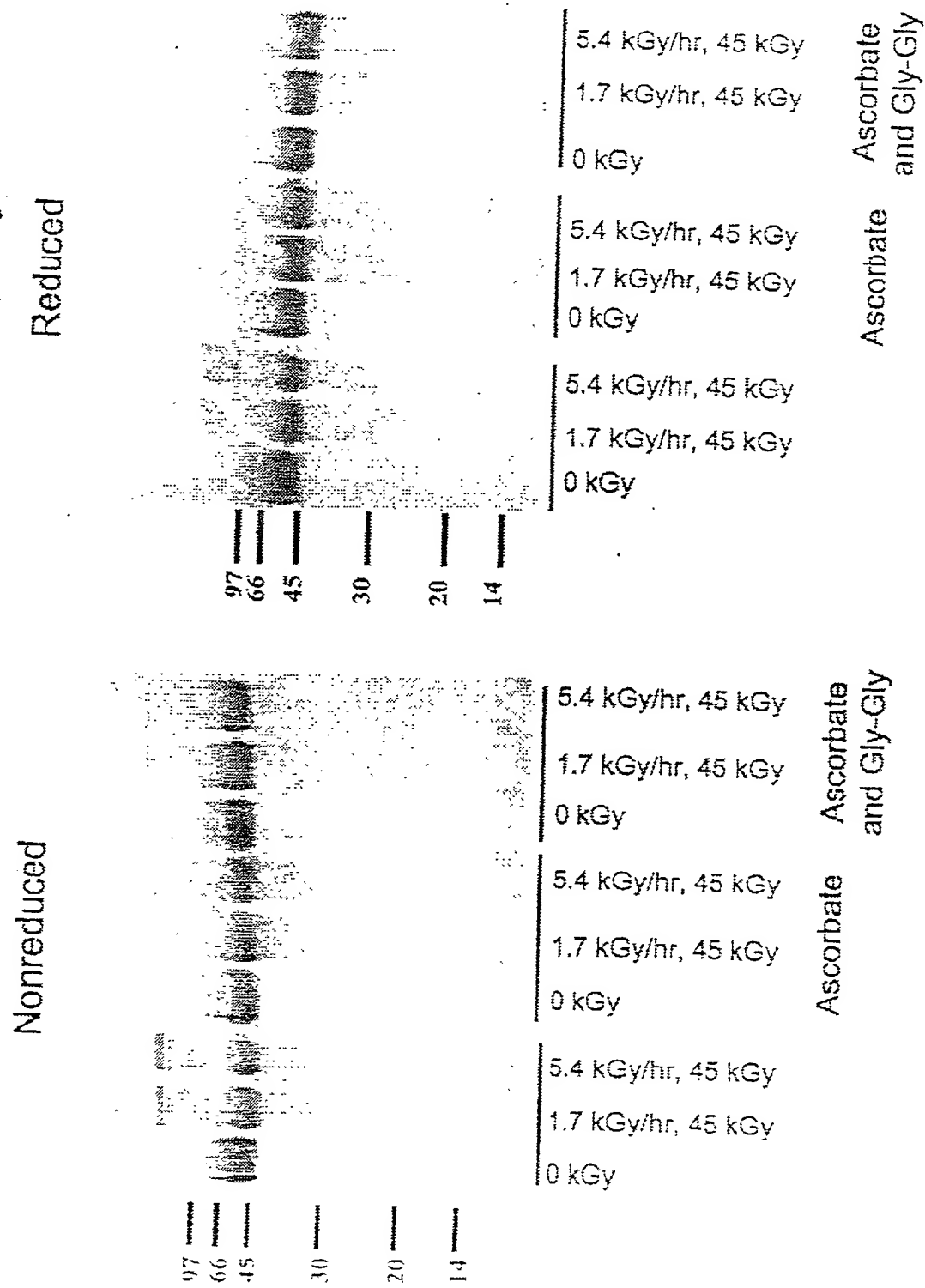


Figure 2A

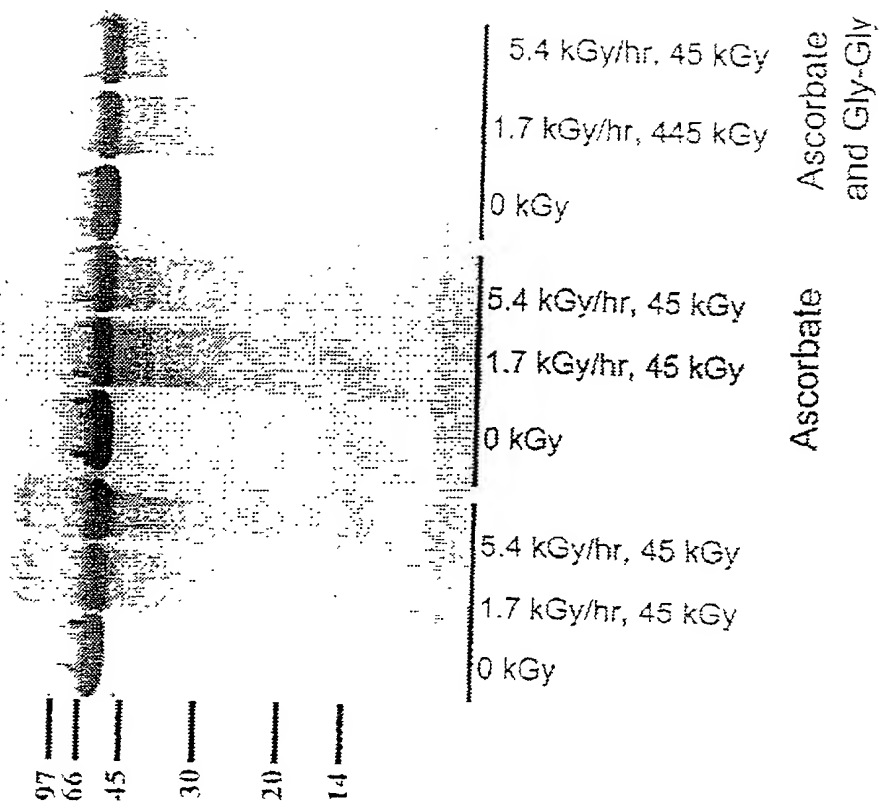
Gamma Irradiation of a Glycosidase In the Presence of Ascorbate and Gly-Gly



TOPTOT 850E2000

Gamma Irradiation of a Sulfatase In the Presence of Ascorbate and Gly-Gly

Reduced



Enlargement of Peak at 30-32 Minutes

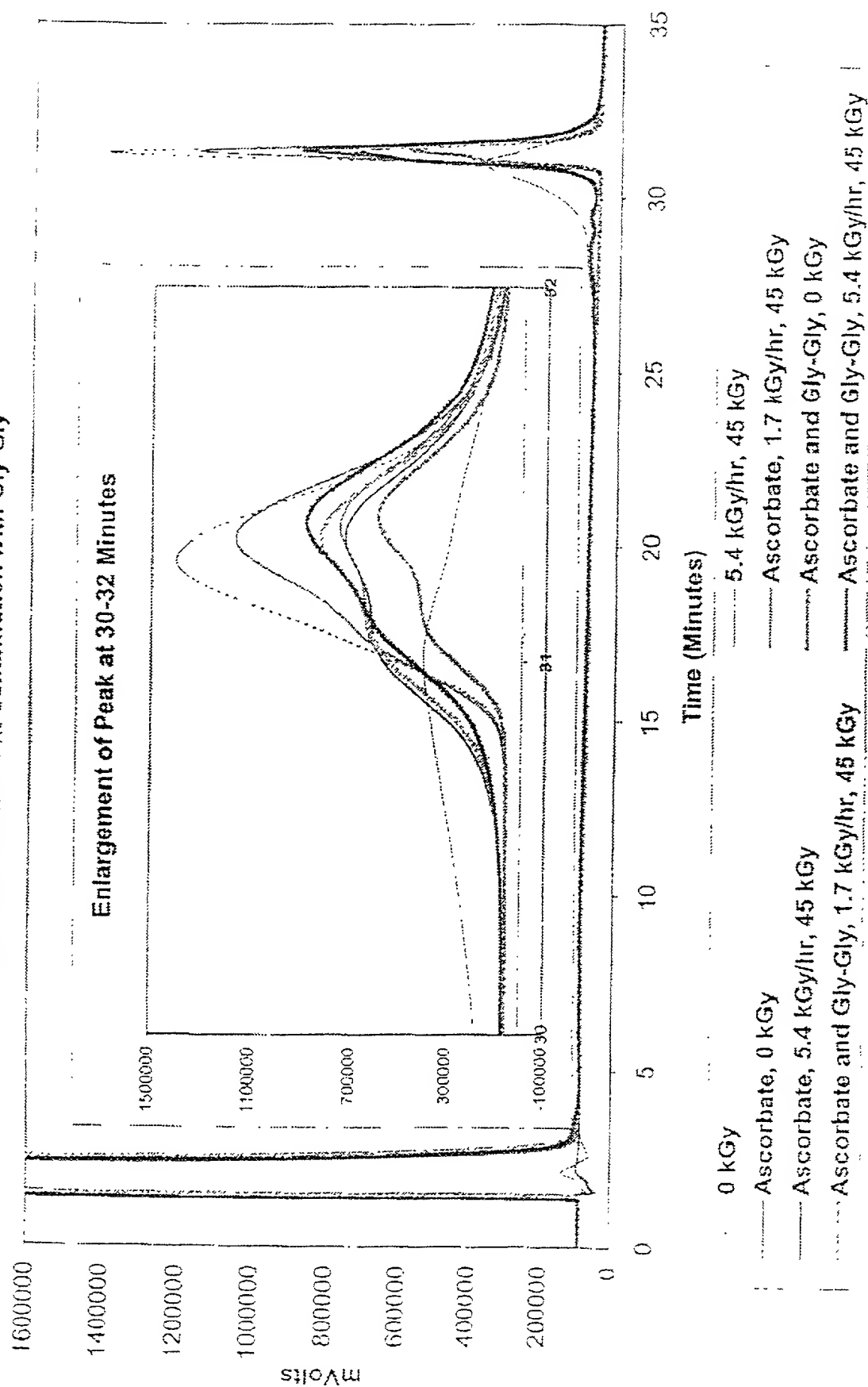
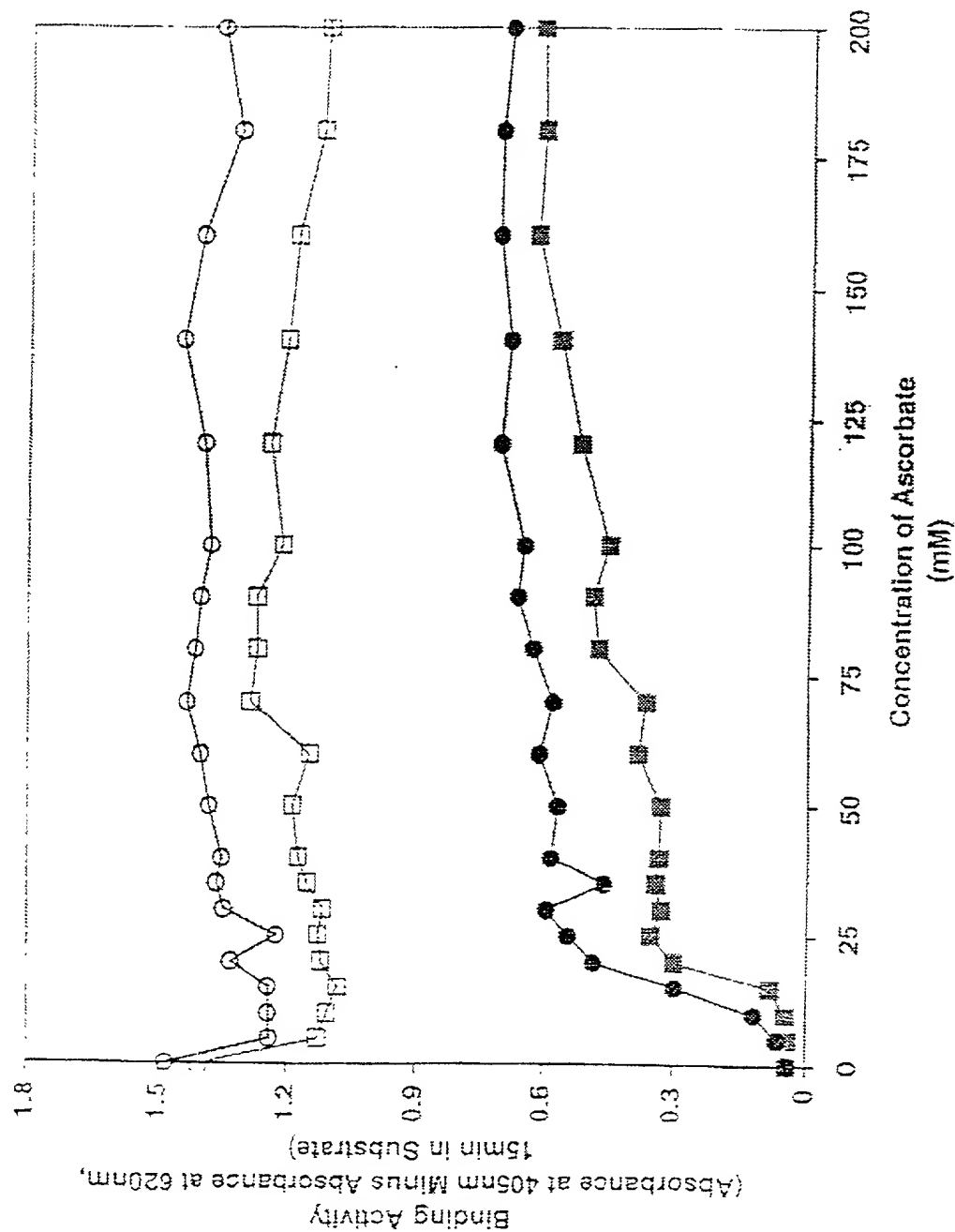


Figure 1 is a line graph showing the effect of ascorbate concentration on uric acid binding activity. The Y-axis is labeled "Binding Activity (Absorbance at 405nm Minus Absorbance at 620nm, 15min in Substrate)" and ranges from 0 to 1.8. The X-axis is labeled "Concentration of Ascorbate (mM)" and ranges from 0 to 200. There are four data series plotted:

- 0kGy (open squares): This series shows the lowest binding activity, starting near 0 at 0 mM ascorbate and increasing to approximately 1.1 at 200 mM.
- Uric Acid, 0kGy (open circles): This series shows slightly higher binding activity than the 0kGy series, starting near 0 at 0 mM ascorbate and increasing to approximately 1.4 at 200 mM.
- 45kGy (filled squares): This series shows higher binding activity than the 0kGy series, starting near 0 at 0 mM ascorbate and increasing to approximately 1.6 at 200 mM.
- Uric Acid, 45kGy (filled circles): This series shows the highest binding activity, starting near 0 at 0 mM ascorbate and increasing to approximately 1.7 at 200 mM.

The graph indicates that binding activity increases with ascorbate concentration for all conditions, and that the 45kGy condition results in higher binding activity compared to the 0kGy condition.



Gamma Irradiation of Immobilized Anti-Insulin Monoclonal Antibody with Varying Ascorbate Concentrations in the Presence or Absence of 2.25mM Uric Acid

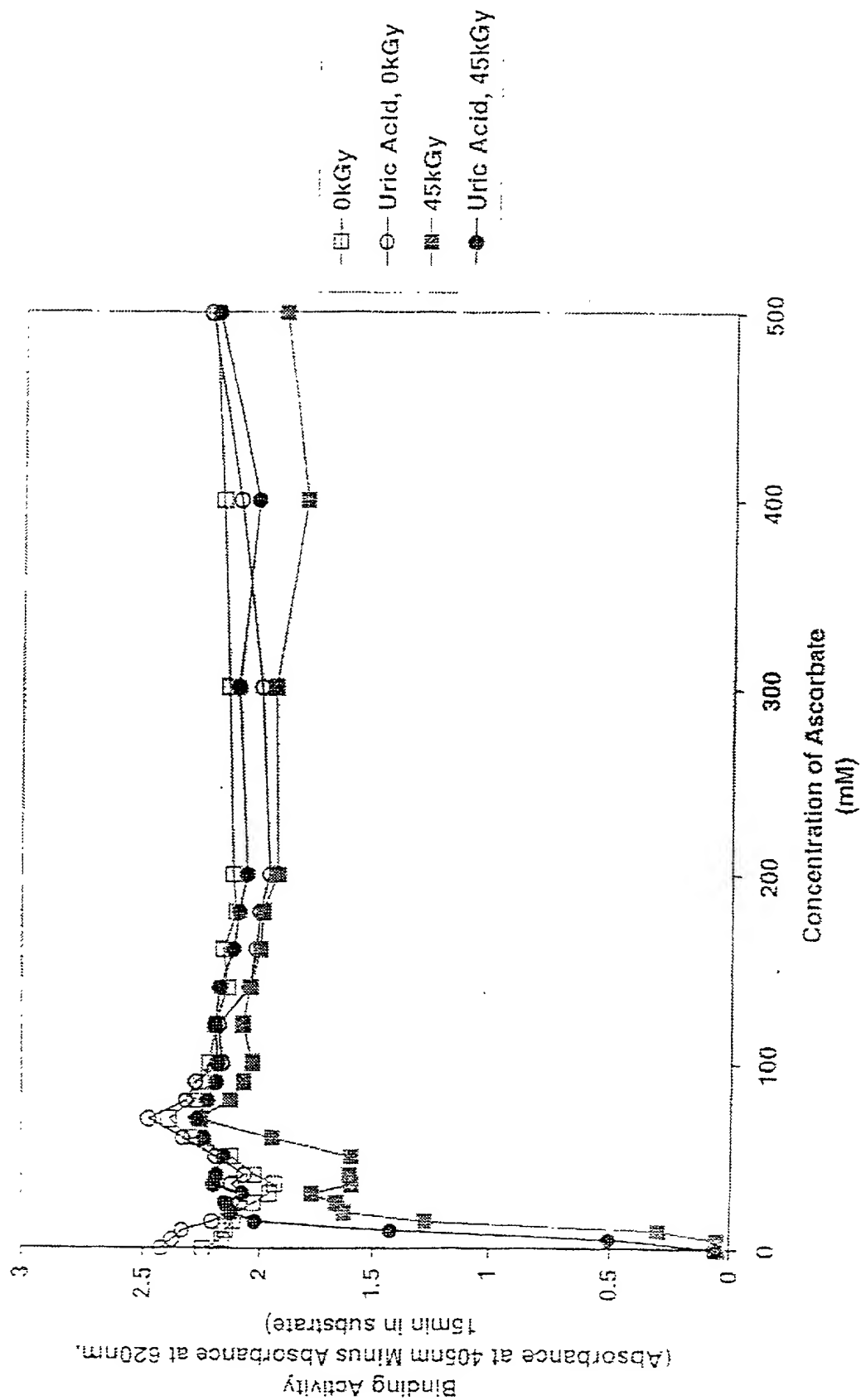
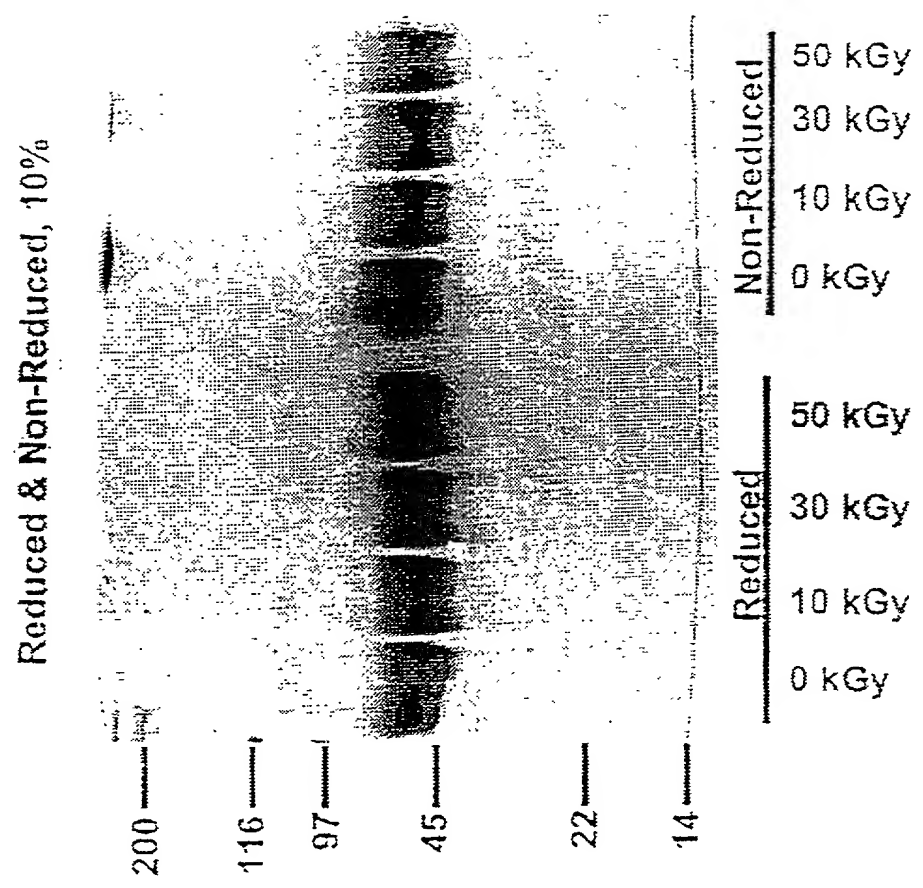


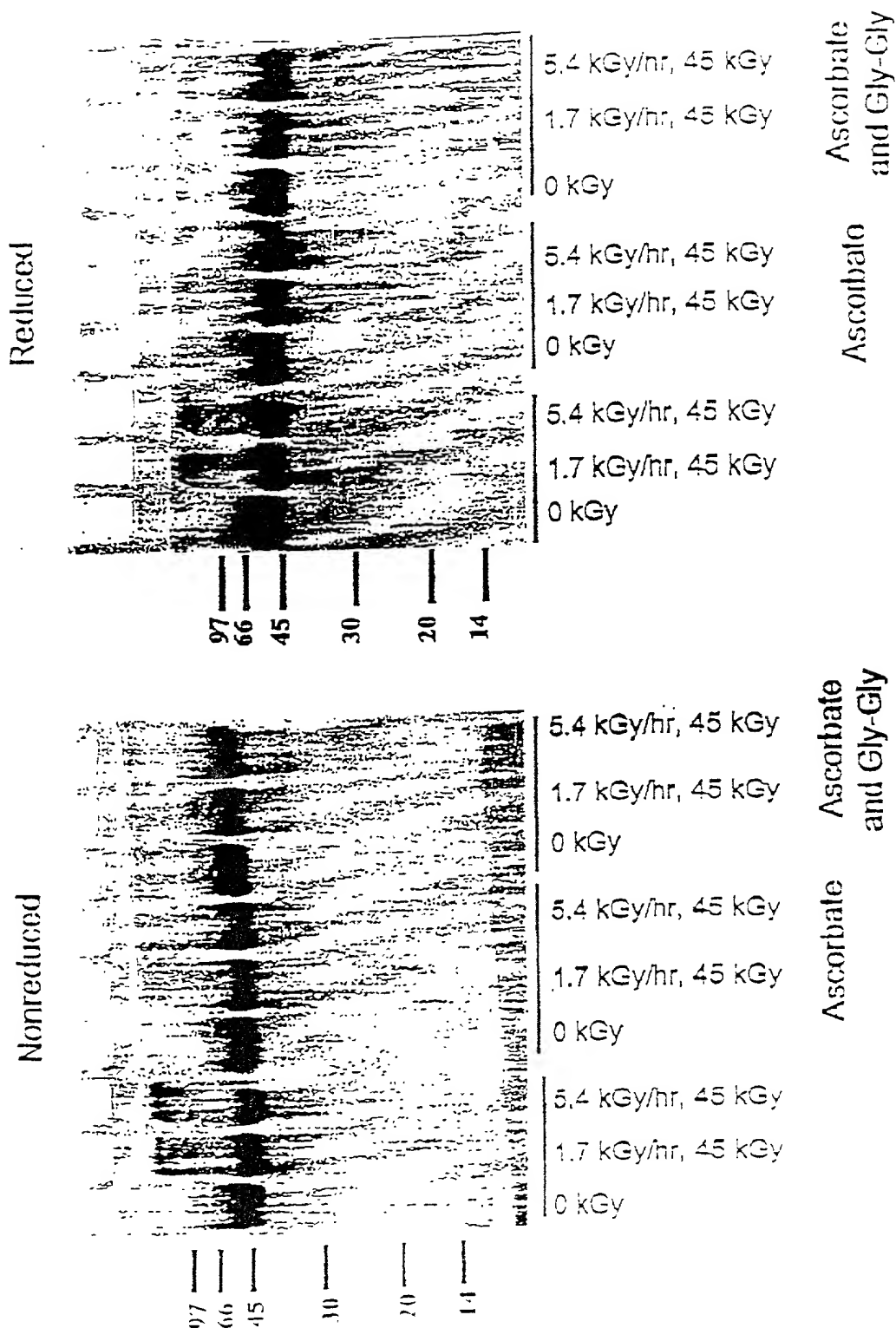
Figure 6

101101-355E2660

Gamma Irradiation of a Lyophilized Galactosidase
In the Presence of 200mM Ascorbate and 200mM Gly-Gly



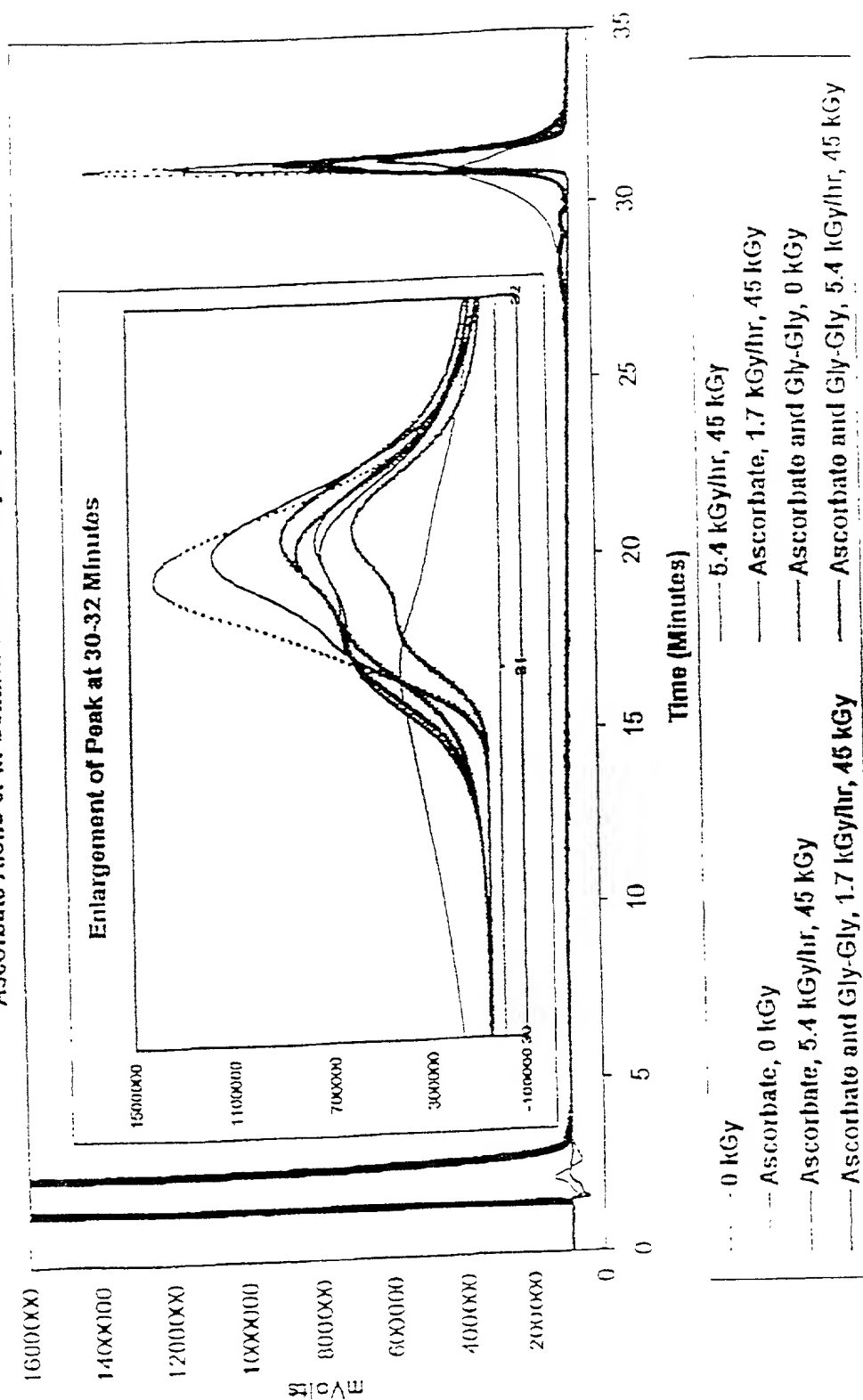
Gamma Irradiation of a Galactosidase in the Absence or Presence of Ascorbate Alone or in Combination with Gly-Gly



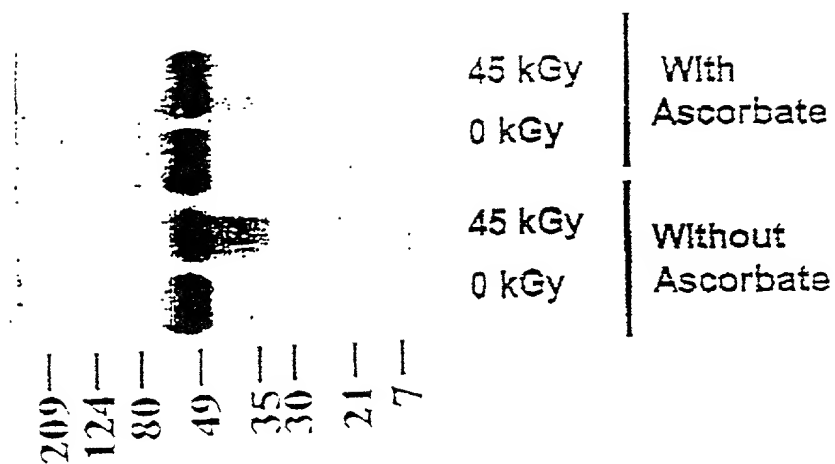
7A

7B

Gamma Irradiation of a Galactosidase in the Presence or Absence of Ascorbate Alone or in Combination with Gly-Gly



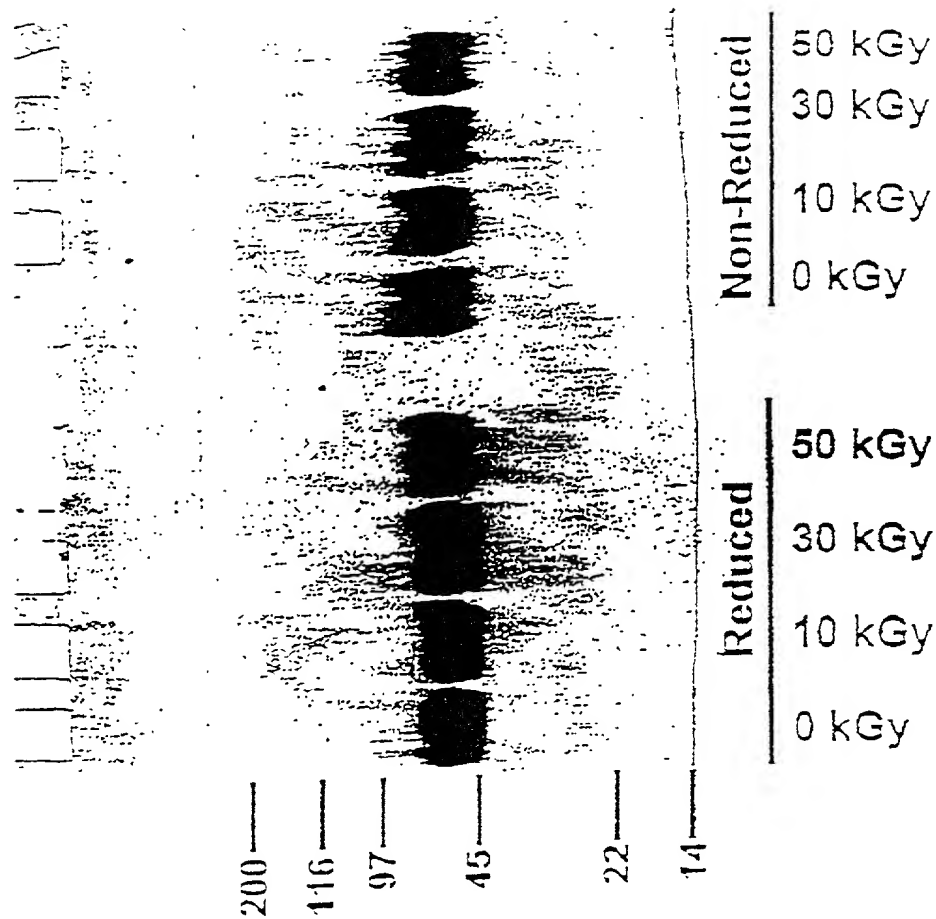
Gamma Irradiation of a Lyophilized Galactosidase in the Absence and Presence of 100mM Ascorbate



9

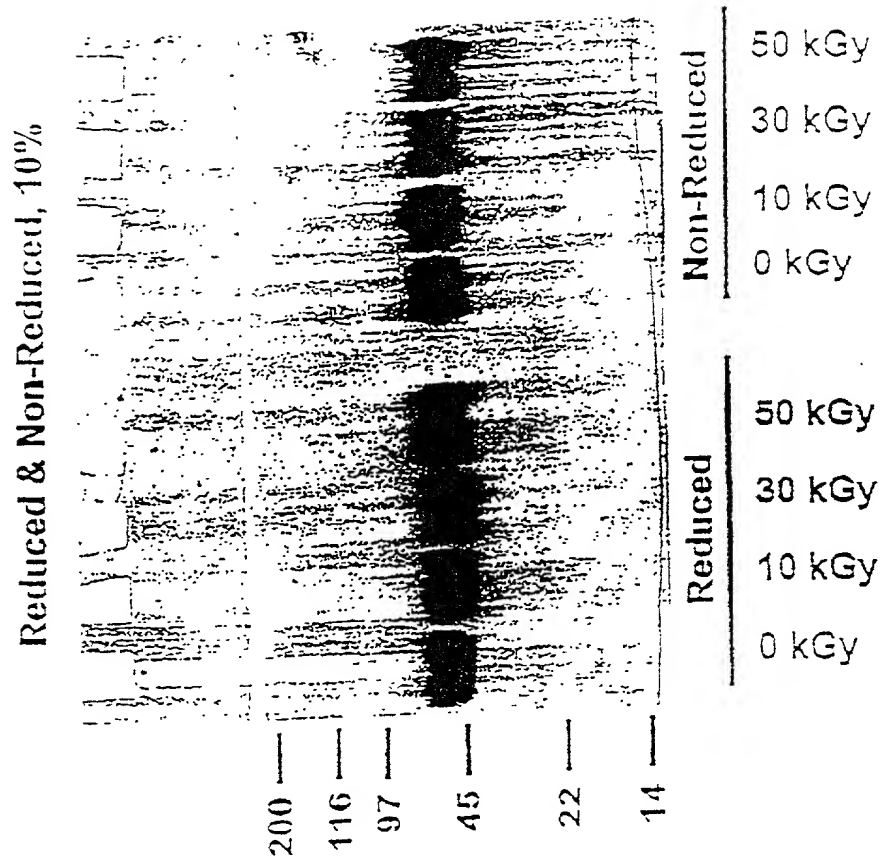
Gamma Irradiation of a Lyophilized Galactosidase In the Absence of Stabilizers

Reduced and Non-Reduced, 10%



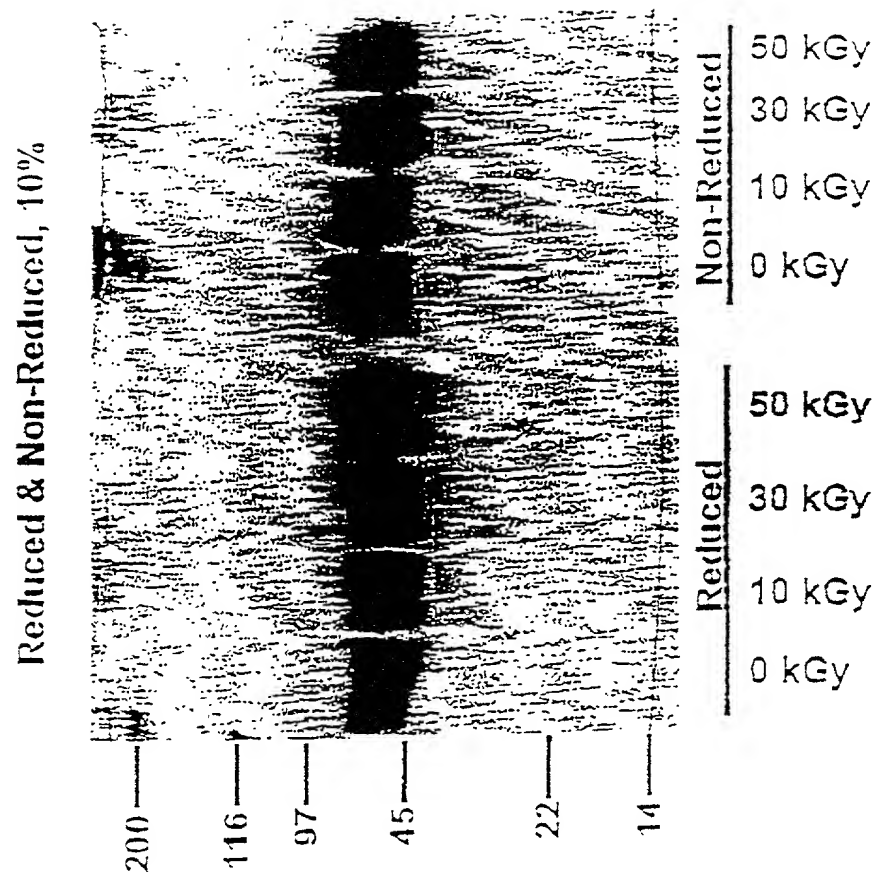
10A

Gamma Irradiation of a Lyophilized Galactosidase In the Presence of 200mM Ascorbate



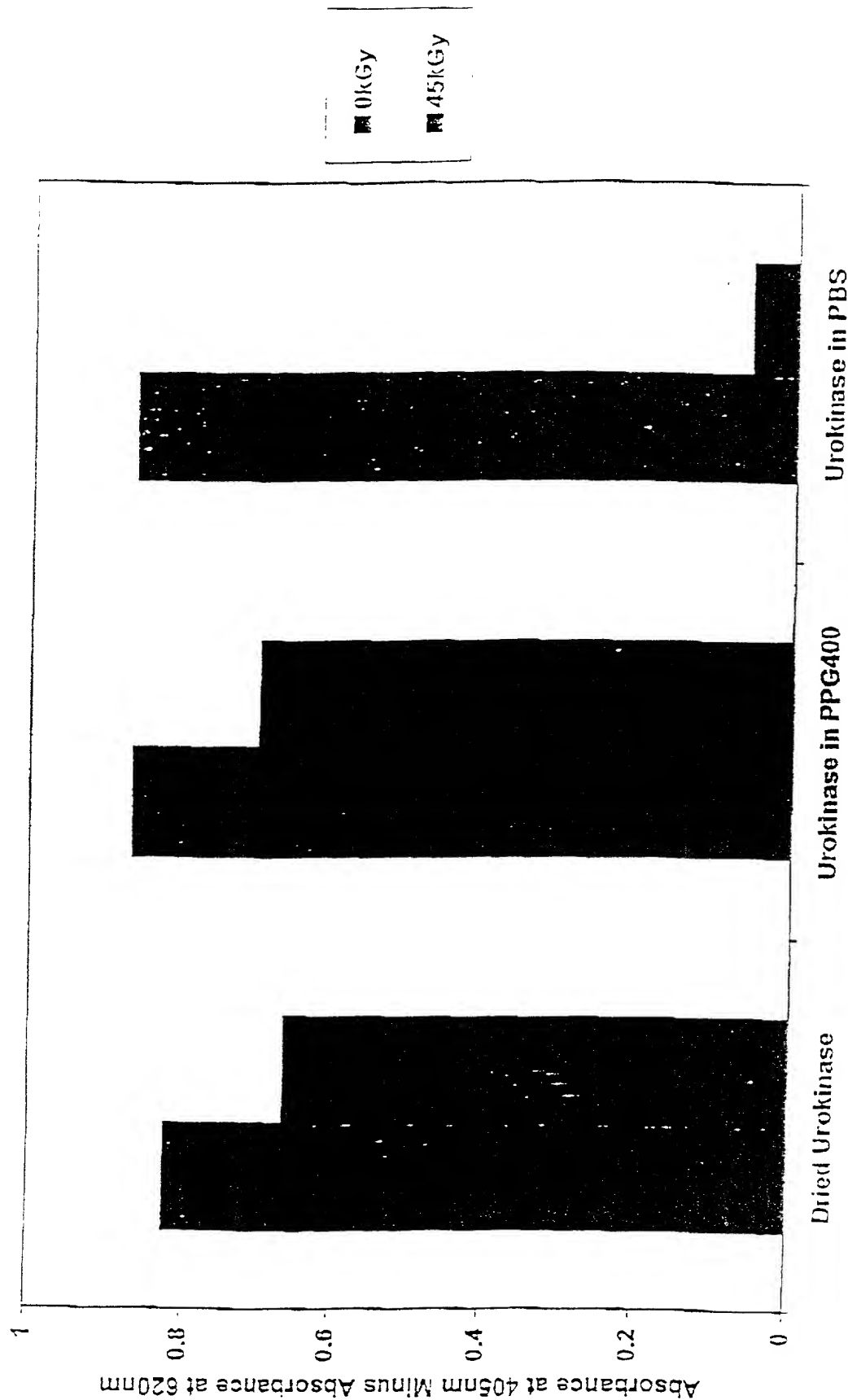
108

Gamma Irradiation of a Lyophilized Galactosidase In the Presence of 200mM Ascorbate and 200mM Gly-Gly

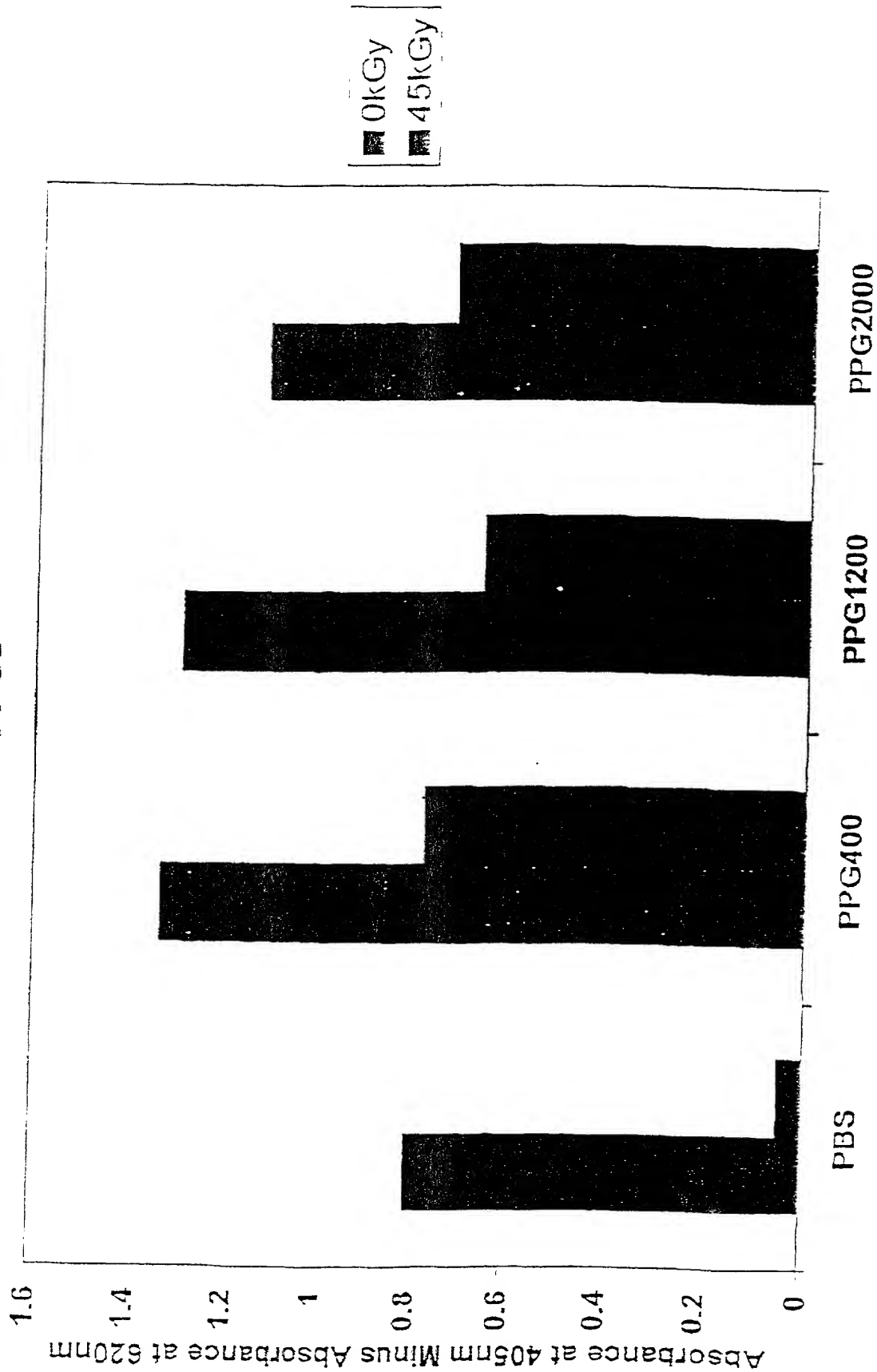


100

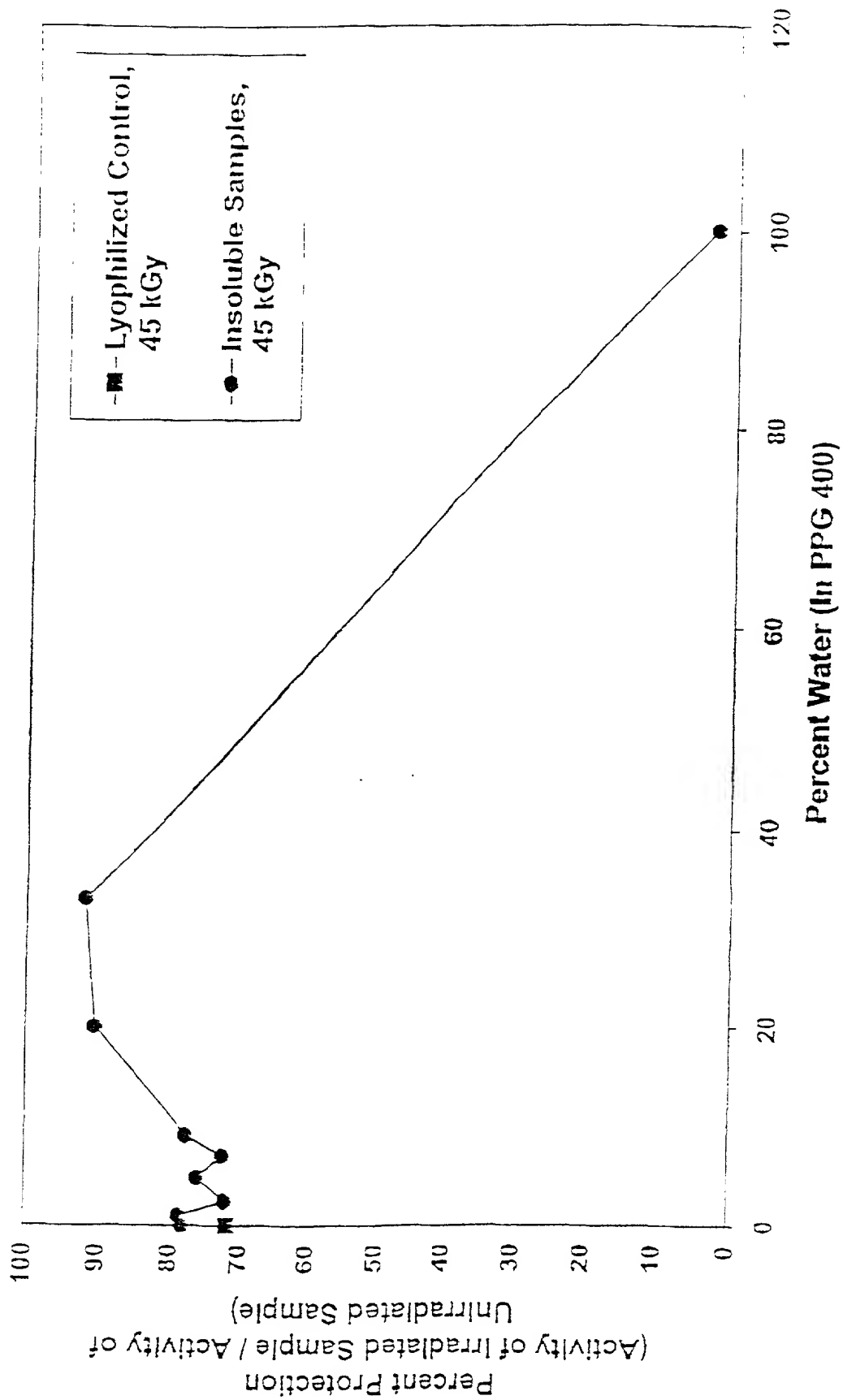
Gamma Irradiation of Dried Urokinase Suspended in PPG400



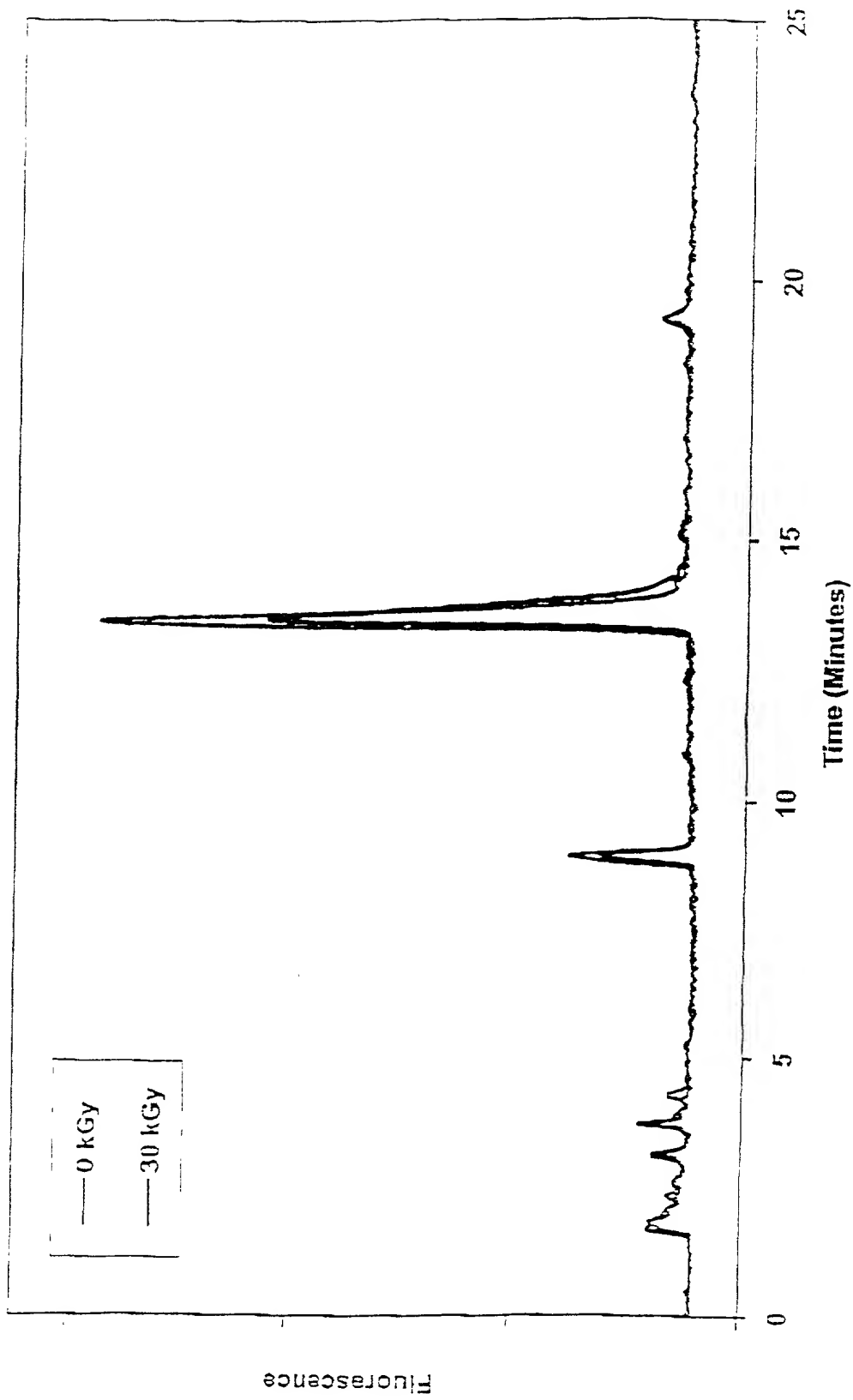
Gamma Irradiation of Immobilized Monoclonal Antibody in the Presence of various PPGs



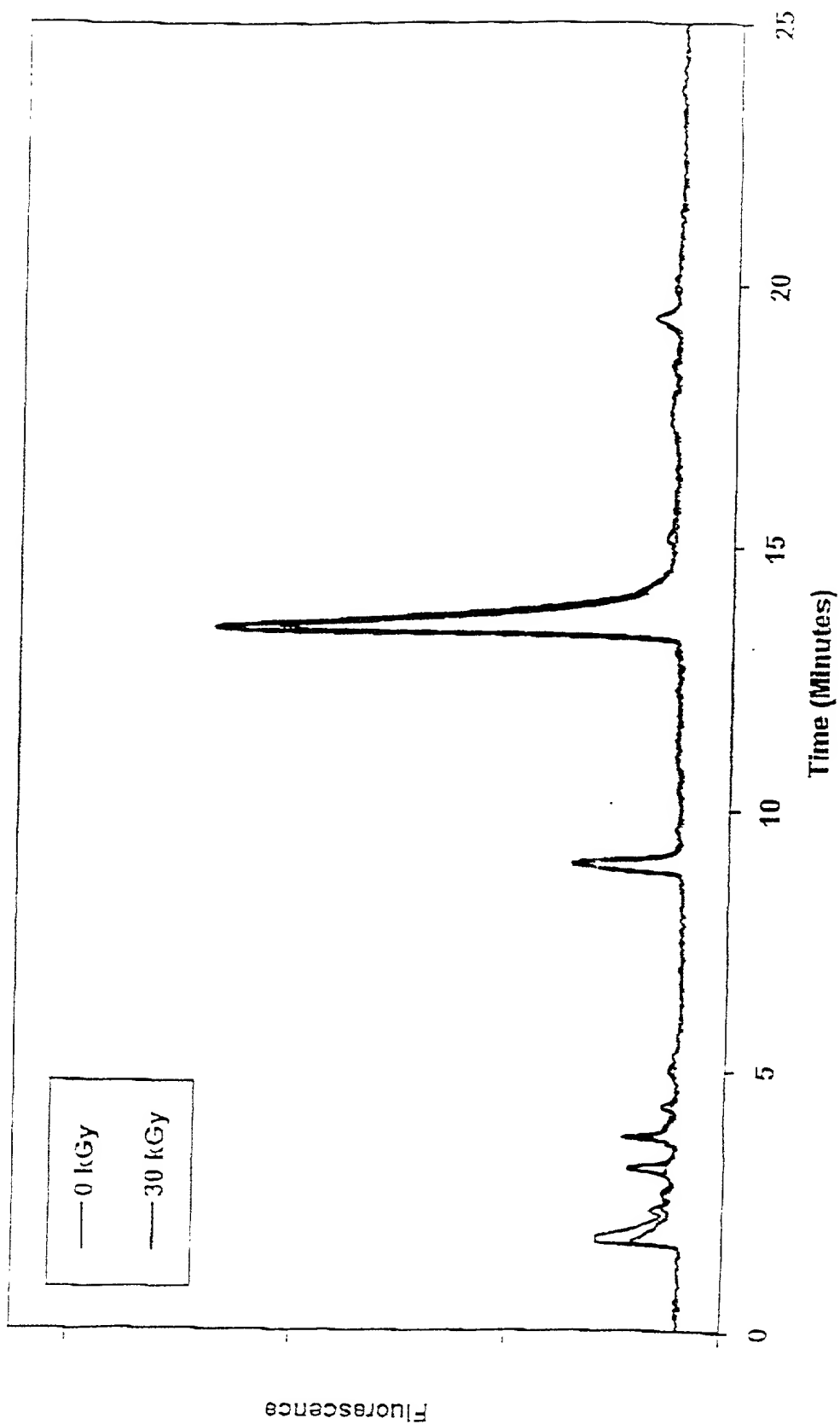
Gamma Irradiation of Trypsin in the Presence of Increasing Amounts of Added Moisture



Gamma Irradiation of Hydrolyzed Heart Valve Cusps in the Presence of PPG 400

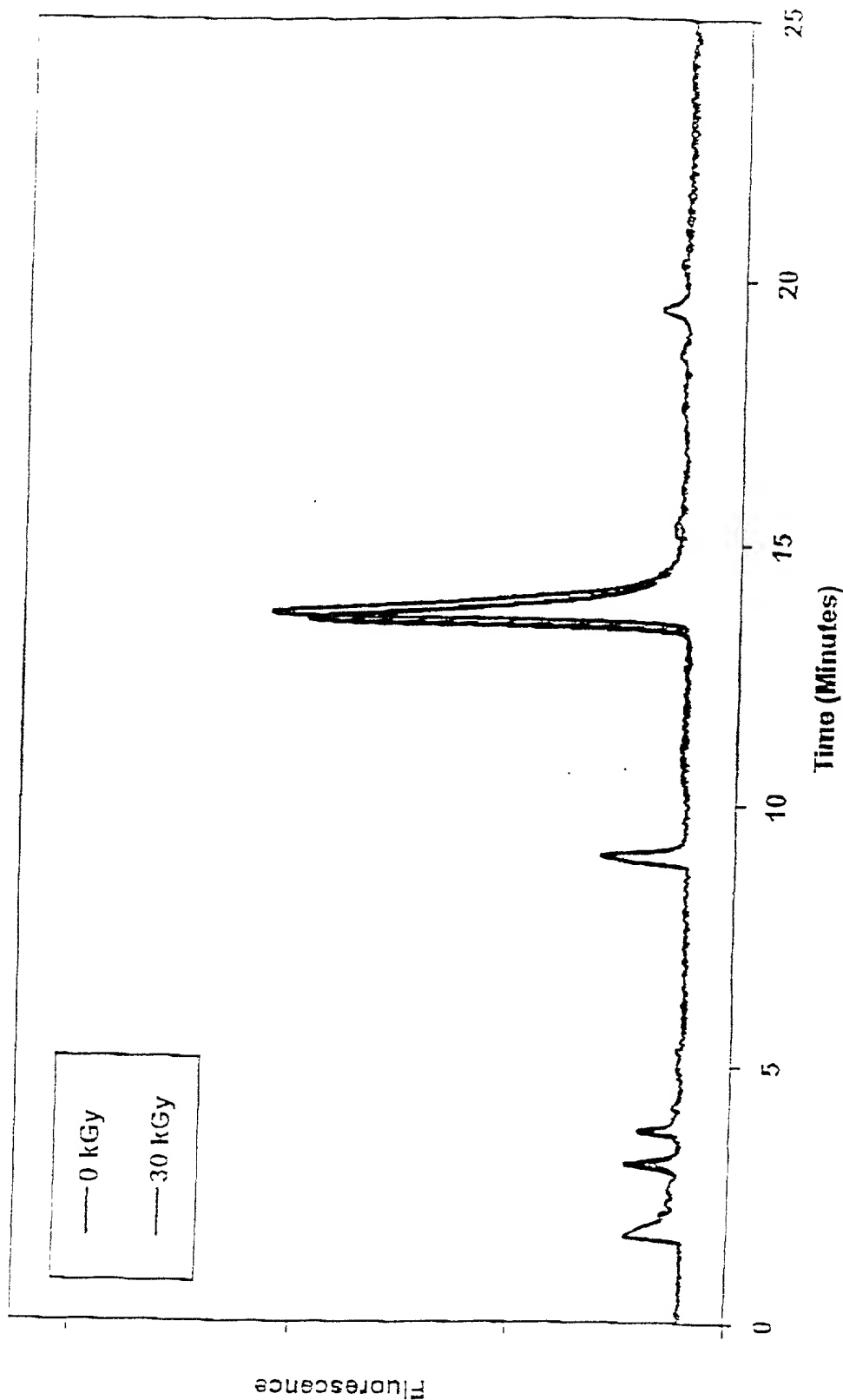


Gamma Irradiation of Hydrolyzed Heart Valve Cusps in the Presence of PPG 400 and 125 mM Trolox C



HB

Gamma Irradiation of Hydrolyzed Heart Valve Cusps in the Presence
of PPG 400 and a Stabilizer Mixture of 62.5mM TroloxG, 100mM Lipic
Acid, 100mM Coumaric Acid, and 100mM n-Propyl Gallate

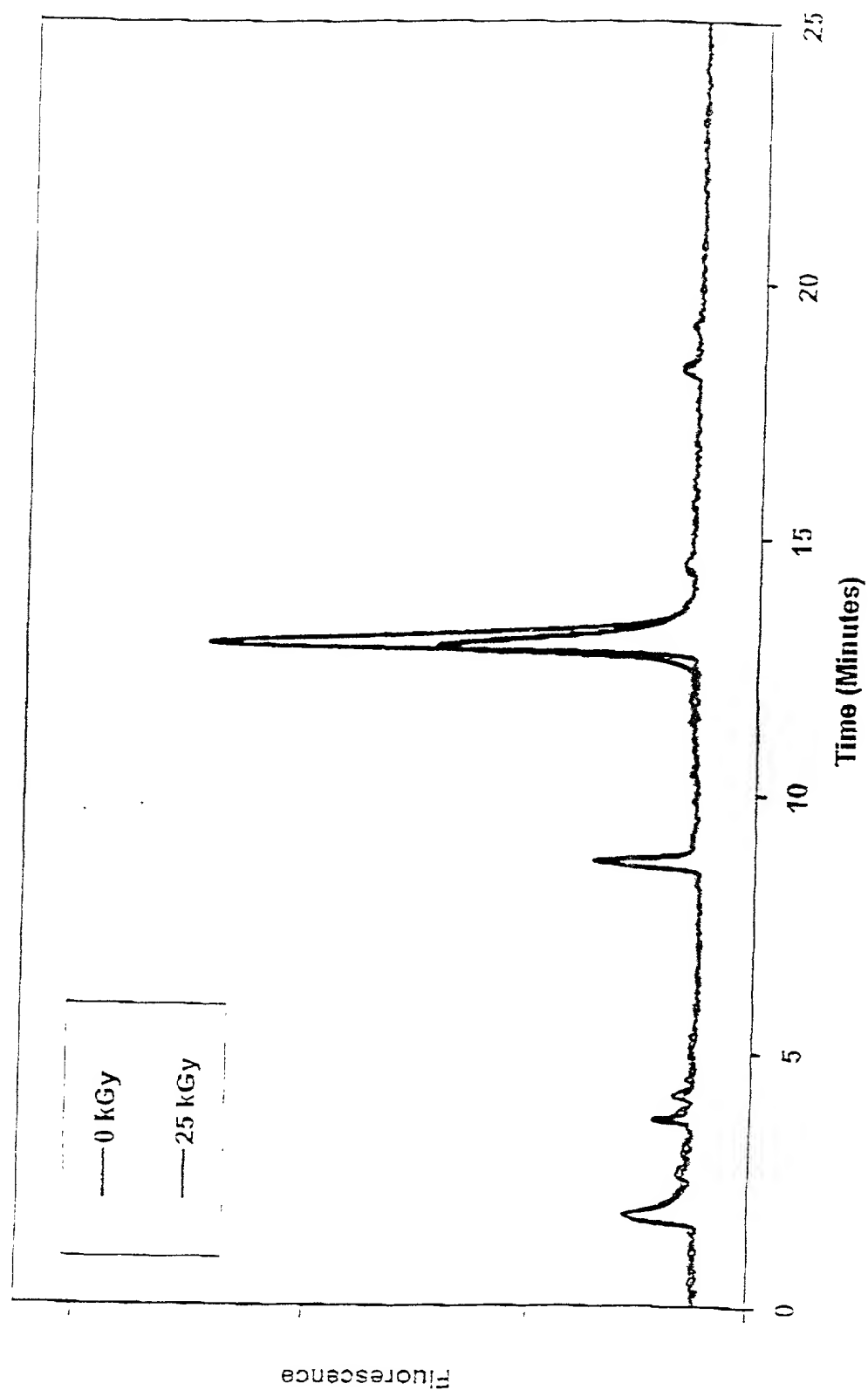


14C

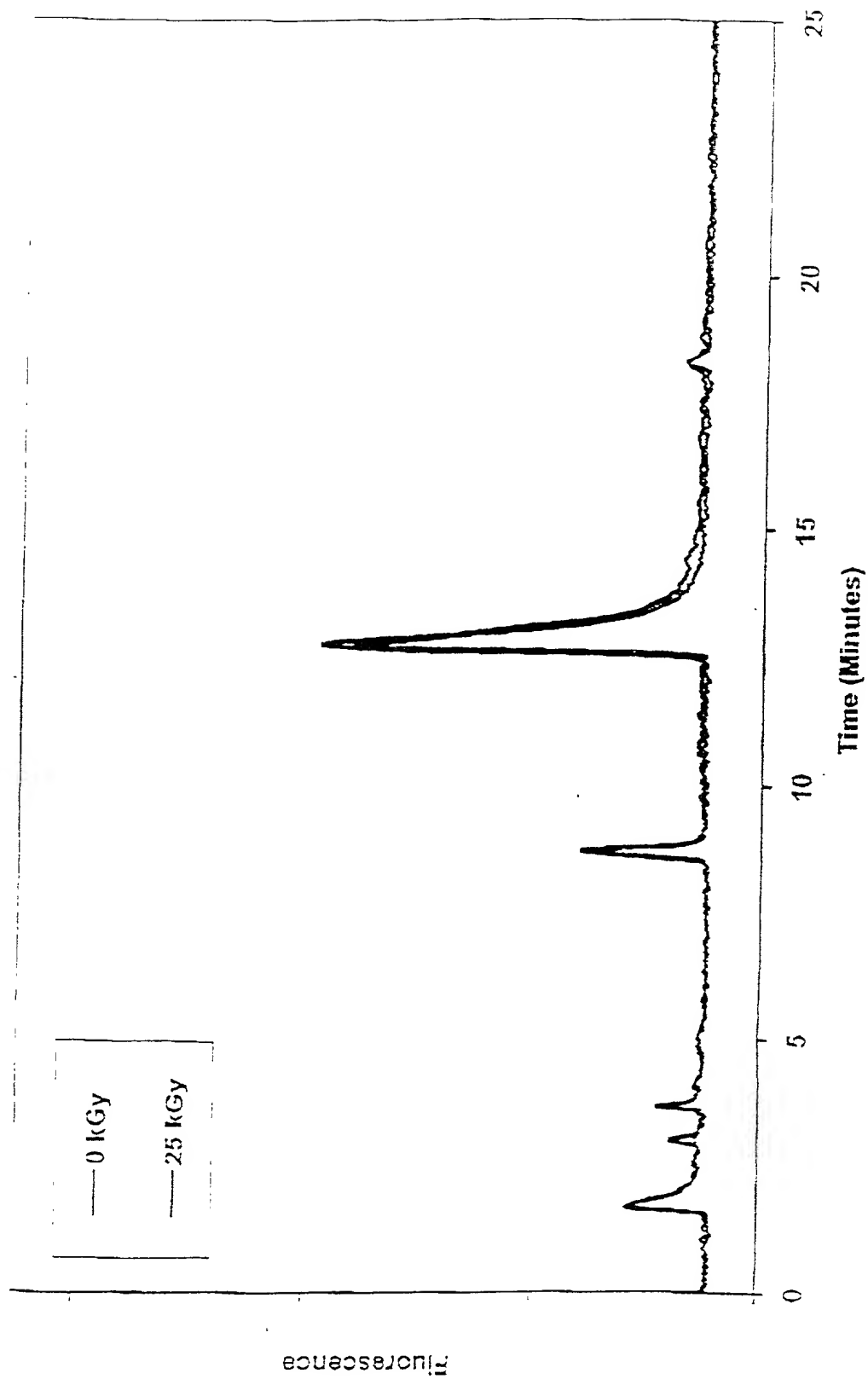
Gamma Irradiation of Porcine Heart Valve Cusps in the Presence of PPG400 with Various Stabilizers

Reduced		
205	1	1. Molecular Weight Markers
119	2	2. Blank
98	3	3. PPG400, 0 kGy
52.3	4	4. PPG400, 30 kGy
36.8	5	5. PPG400 and TroloxG, 0 kGy
30.1	6	6. PPG400 and TroloxG, 30 kGy
22	7	7. PPG400 and a Cocktail of TroloxG, Lipoic Acid, Coumaric Acid, and n-Propyl Gallate, 0 kGy
7.6	8	8. PPG400 and a Cocktail of TroloxG, Lipoic Acid, Coumaric Acid, and n-Propyl Gallate, 30kGy

Gamma Irradiation of Hydrolyzed Heart Valve Cusps in the Presence of PBS

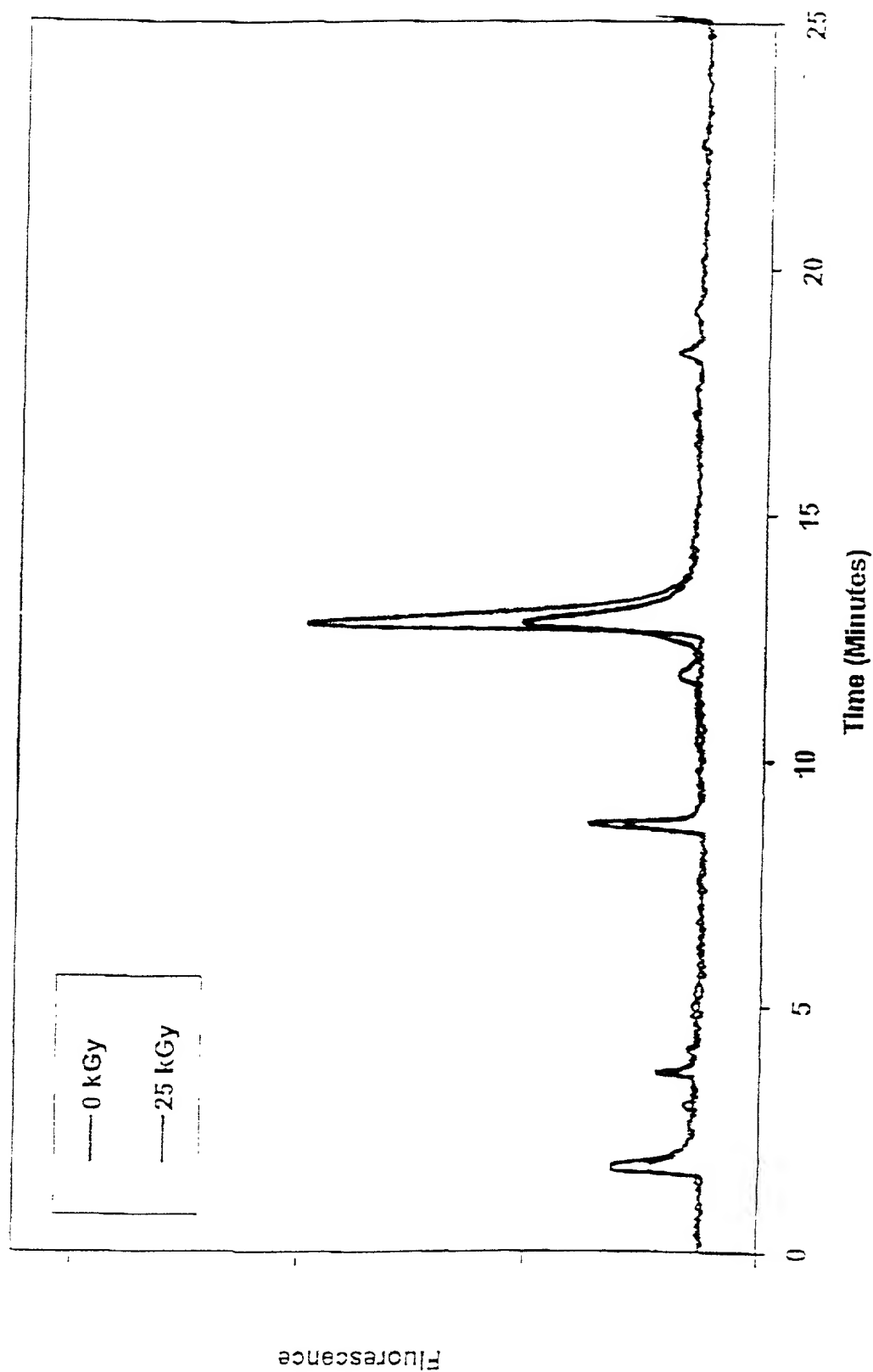


Gamma Irradiation of Hydrolyzed Heart Valve Cusps in the Presence of PPG 400



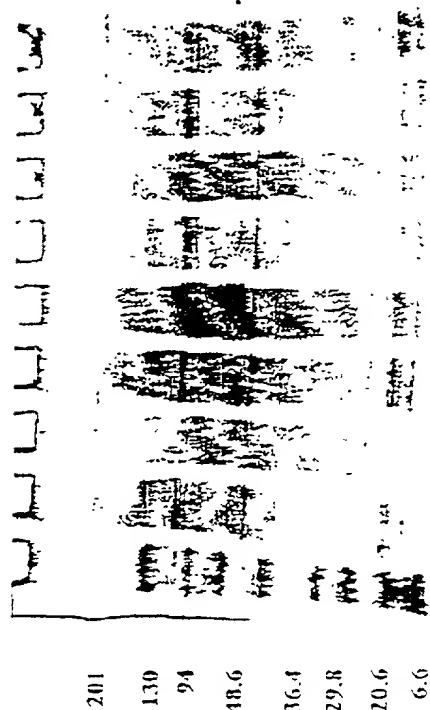
15B

Gamma Irradiation of Hydrolyzed Heart Valve Cusps in the Presence of 50% DMSO



Gamma Irradiation of Porcine Heart Valve Cusps in the Presence of Various Solvents

Reduced



1. Molecular Weight Markers

2. PBS, 0 kGy

3. PBS, 25 kGy

4. PPG400, 0 kGy

5. PPG400, 25 kGy

6. 50% DMSO, 0 kGy

7. 50% DMSO, 25 kGy

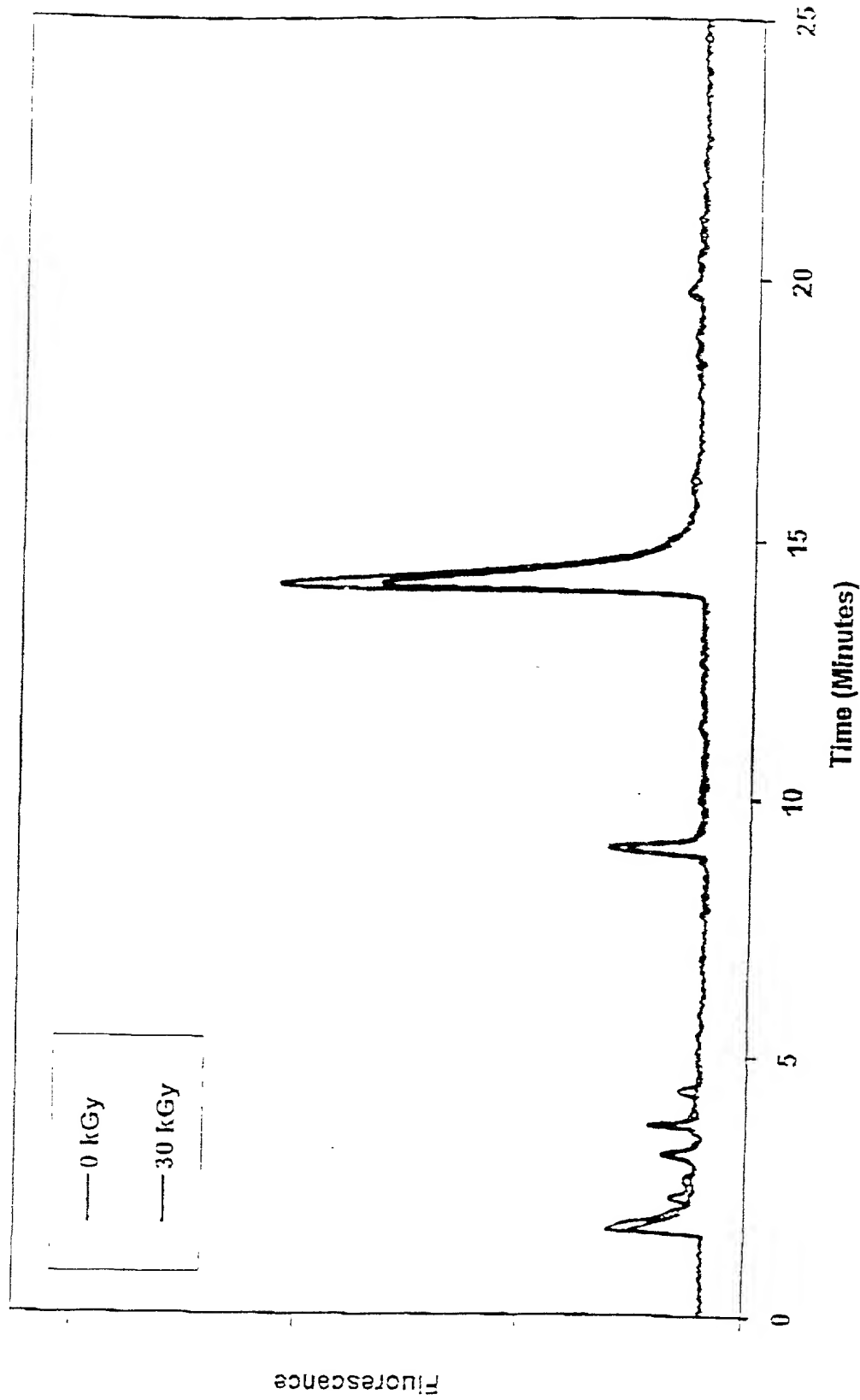
1 2 3 4 5 6 7 8 9

8. 50% DMSO and Cocktail of Ascorbate,
Coumaric Acid, and n-Propyl Gallate, 0 kGy

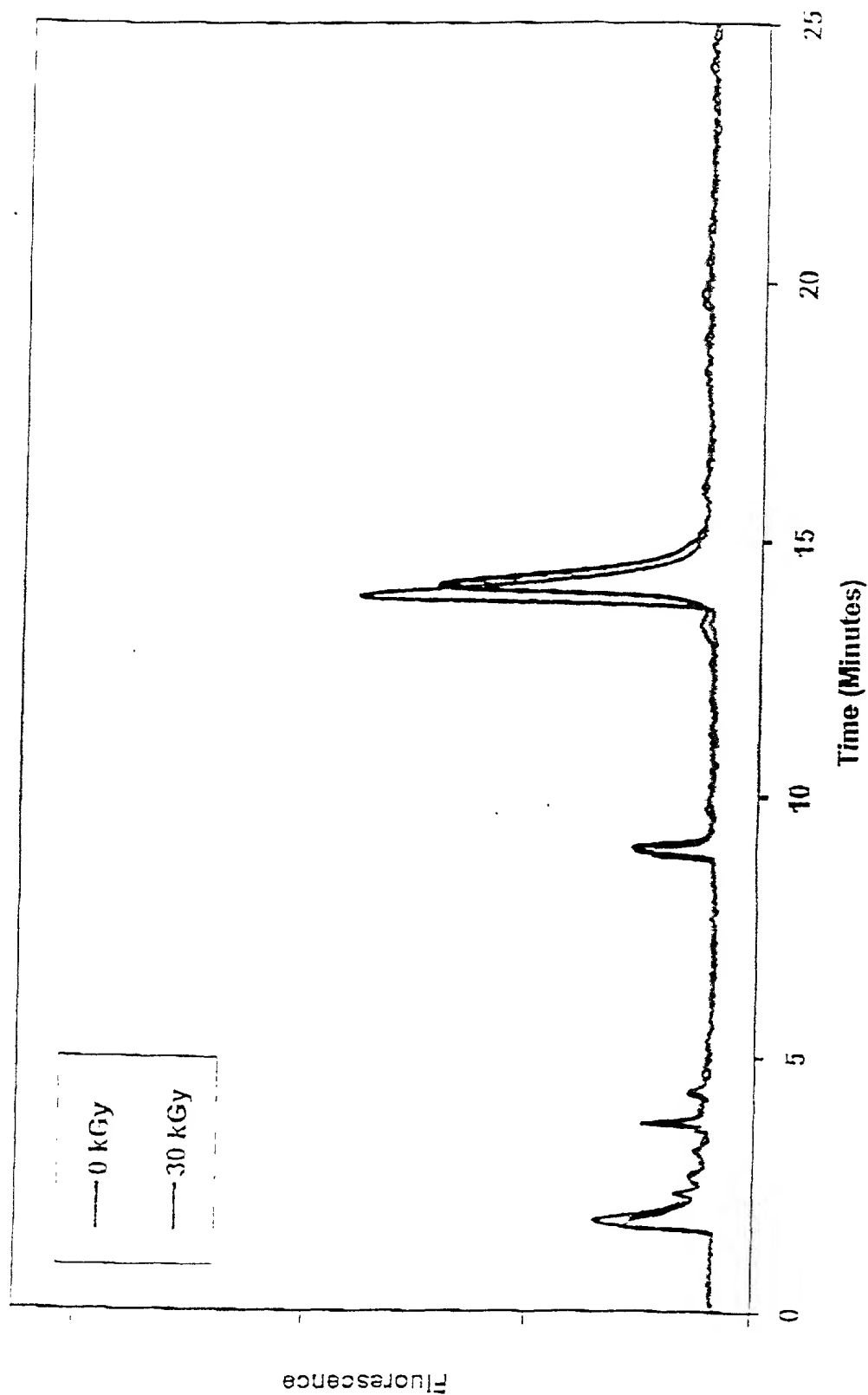
9. 50% DMSO and Cocktail of Ascorbate,
Coumaric Acid, and n-Propyl Gallate, 25 kGy

15E

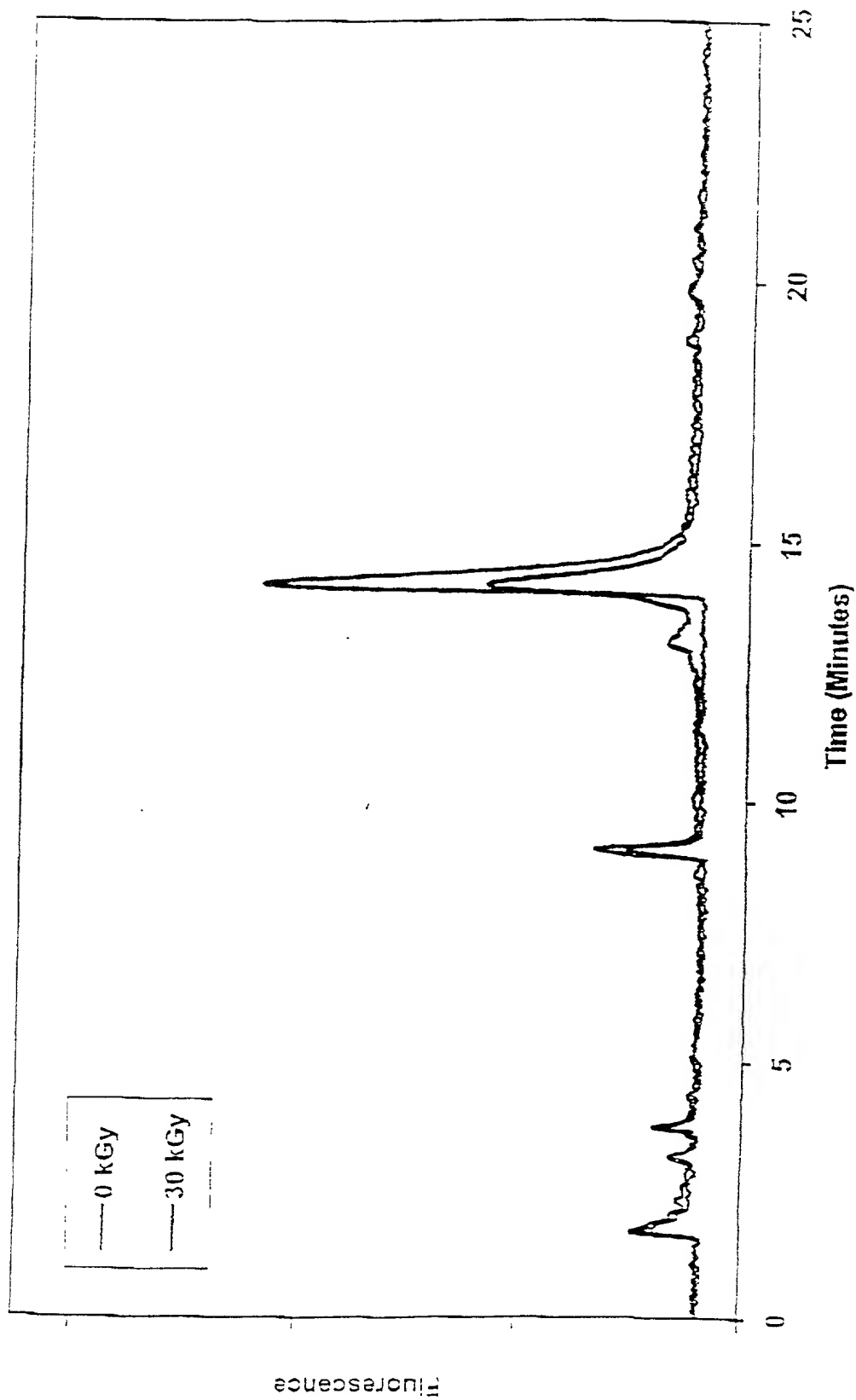
Gamma Irradiation of Hydrolyzed Heart Valve Cusps in the Presence of PBS



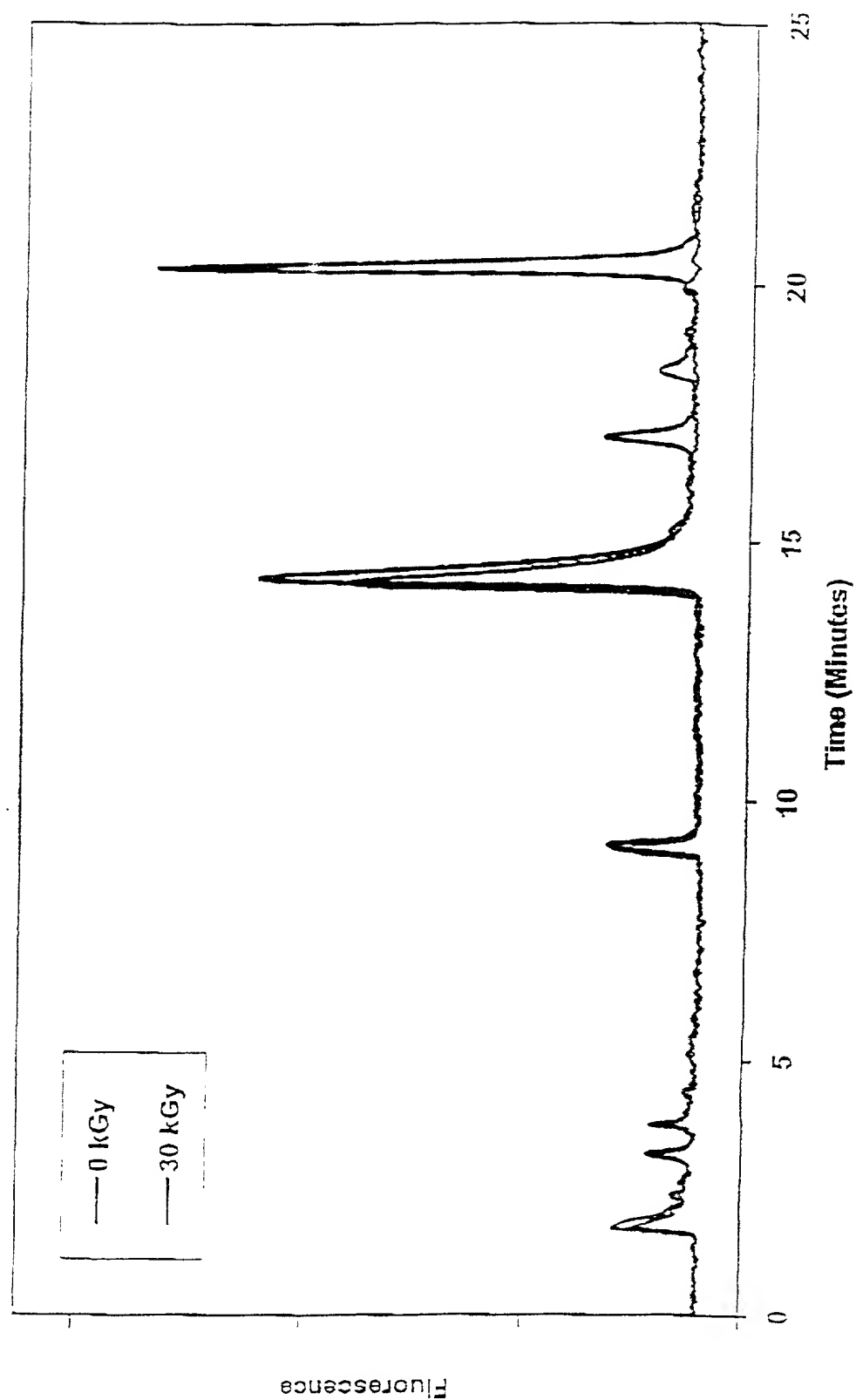
**Gamma Irradiation of Hydrolyzed Heart Valve Cusps in the
Presence of a Cryopreservative (Containing Approximately 20% DMSO)**



Gamma Irradiation of Hydrolyzed Heart Valve Cusps in the Presence of 50% DMSO

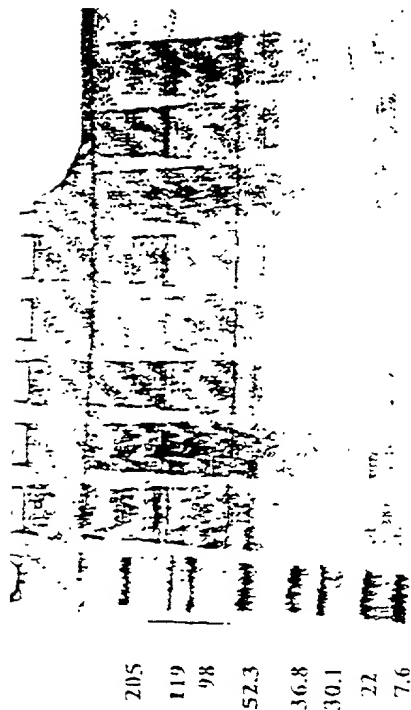


Gamma Irradiation of Hydrolyzed Heart Valve Cusps in the Presence of 50% DMSO and Ascorbate



Gamma Irradiation of Porcine Heart Valve Cusps in the Presence of Various Solvents

Reduced

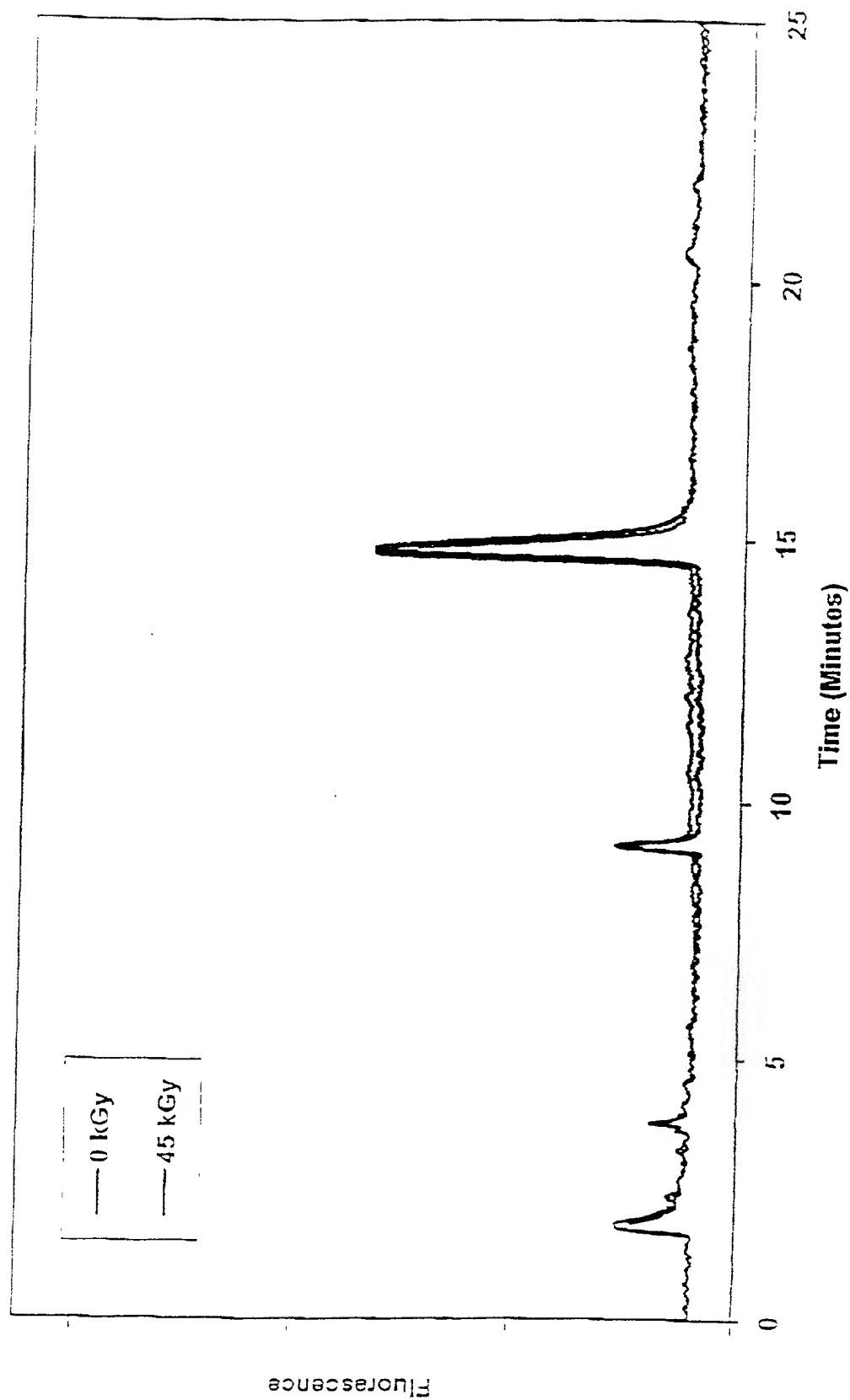


1. Molecular Weight Markers
2. Cryopreservative, 0 kGy
3. Cryopreservative, 30 kGy
4. PBS, 0 kGy
5. PBS, 30 kGy
6. 50% DMSO, 0 kGy
7. 50% DMSO, 30 kGy
8. 50% DMSO and Ascorbate, 0 kGy
9. 50% DMSO and Ascorbate, 30 kGy

1 2 3 4 5 6 7 8 9

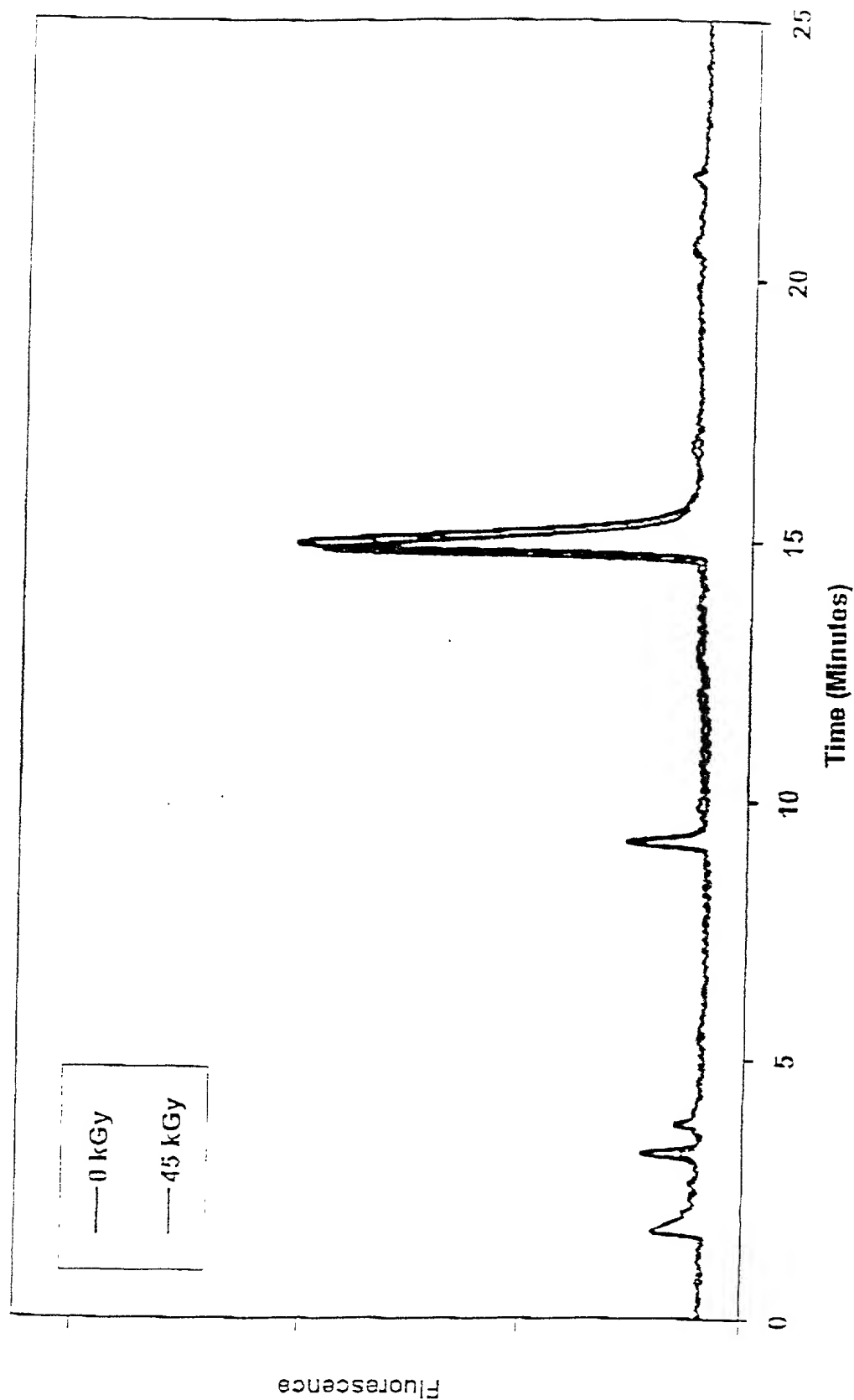
16E

Gamma Irradiation of Hydrolyzed Heart Valve Cusps in the Presence of PBS



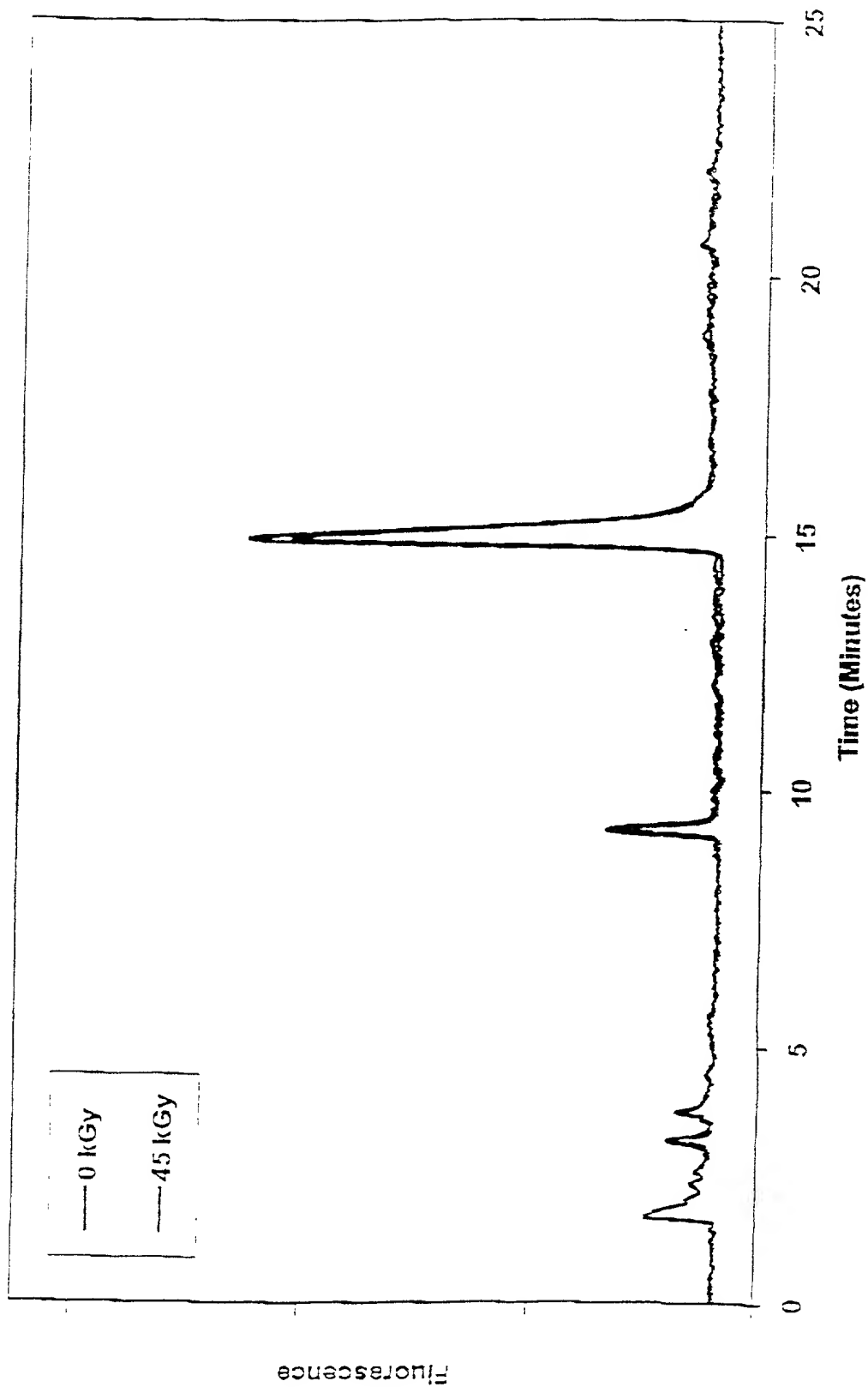
17A

Gamma Irradiation of Hydrolyzed Heart Valve Cusps in the Presence of PBS and Ascorbate



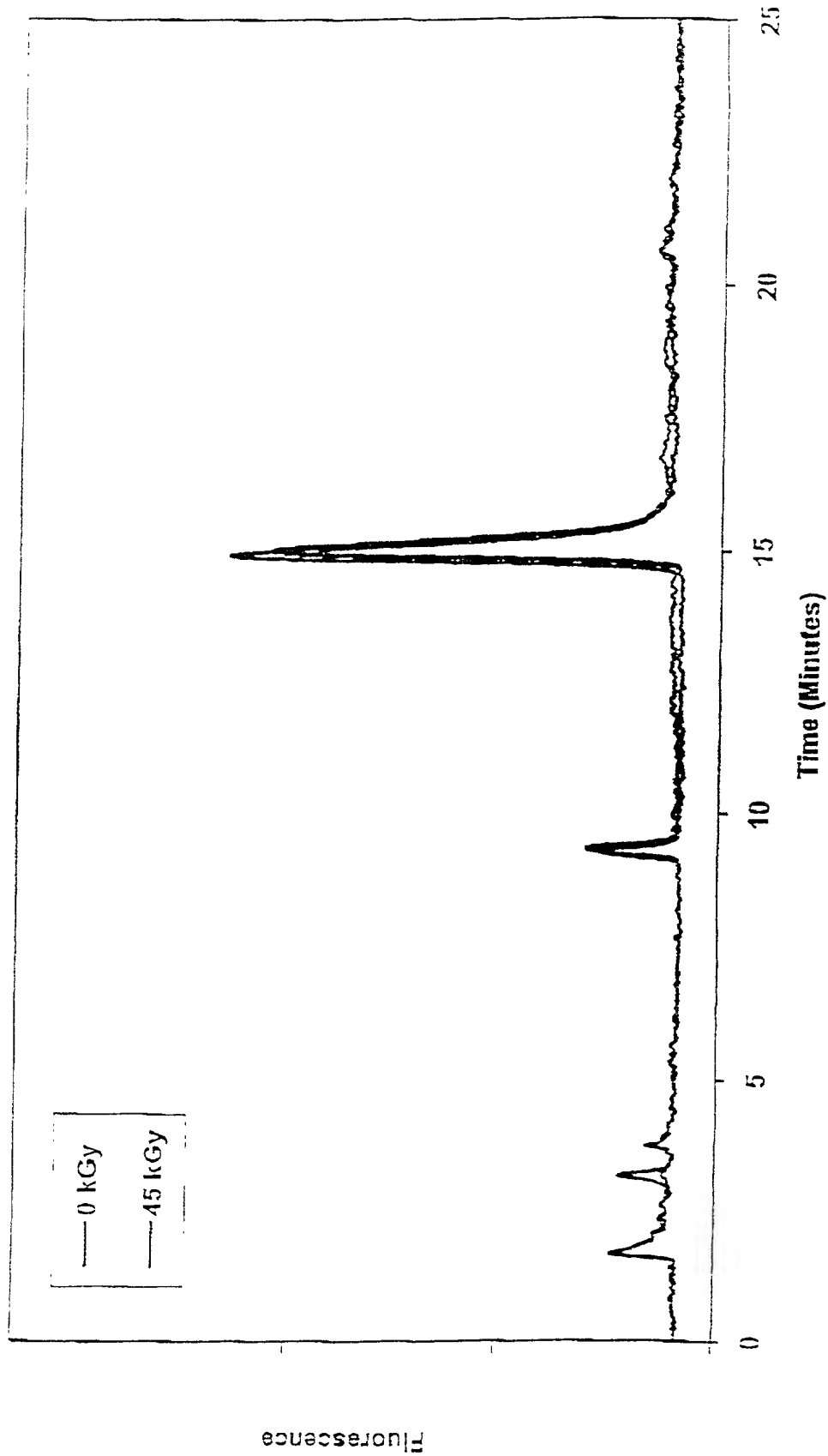
17B

Gamma Irradiation of Hydrolyzed Heart Valve Cusps in the Presence of PPG 400

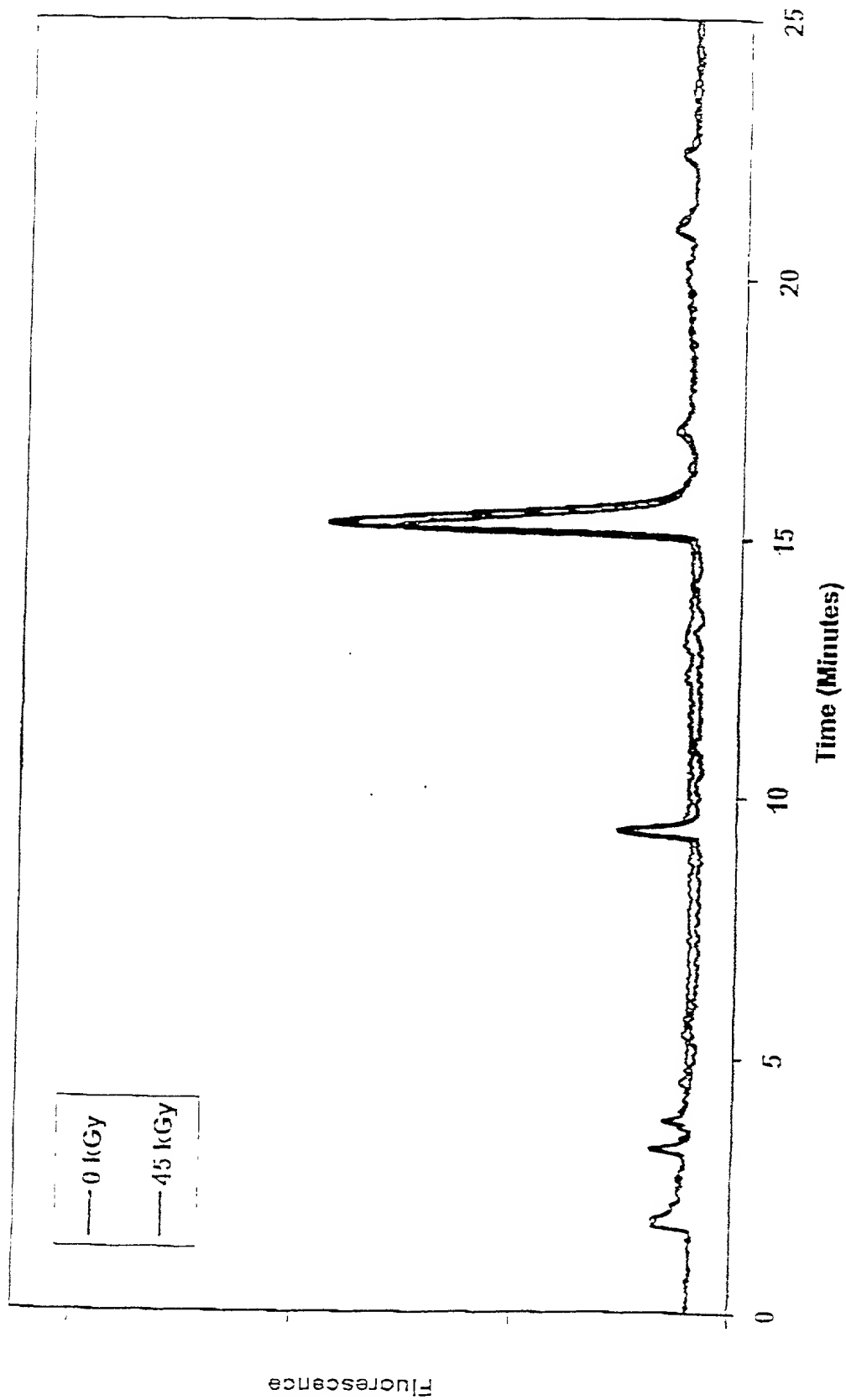


17C

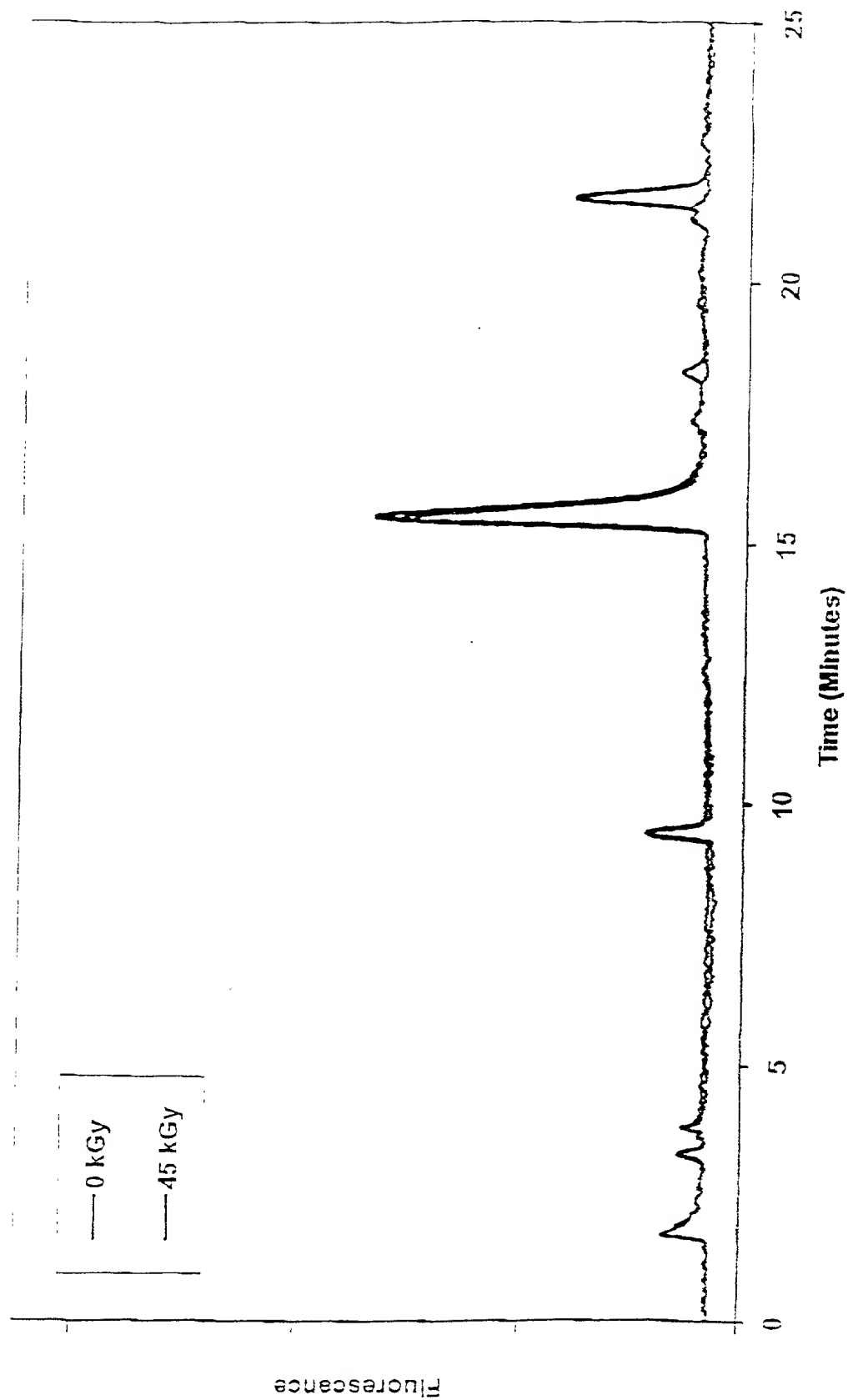
Gamma Irradiation of Hydrolyzed Heart Valve Cusps
Dehydrated with PPG 400 and Rehydrated in the Presence of
PBS and Ascorbate



Gamma Irradiation of Hydrolyzed Heart Valve Cusps in the Presence of 50% DMSO

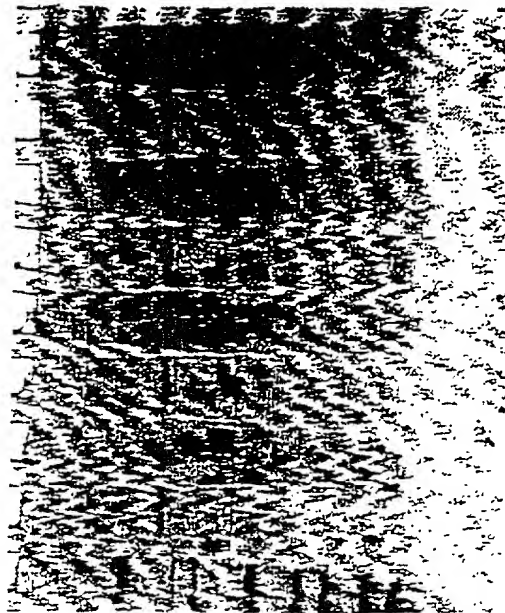


Gamma Irradiation of Hydrolyzed Heart Valve Cusps in the Presence of 50% DMSO and Ascorbate



77

Gamma Irradiation of Porcine Heart Valve Cusps in the Presence of Various Solvents

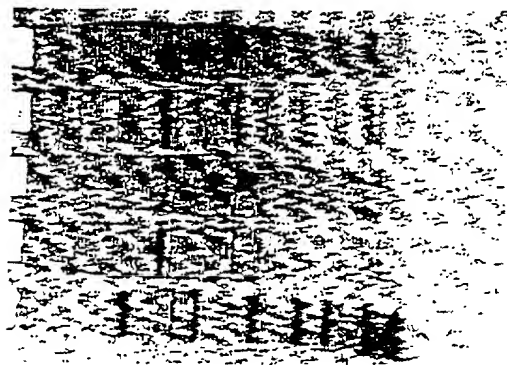


205
119
98
52.3
36.8
30.1
22
7.6

1 2 3 4 5 6 7 8 9

1. Molecular Weight Markers
2. PBS, 0 kGy
3. PBS, 45 kGy
4. PBS and Ascorbate, 0 kGy
5. PBS and Ascorbate, 45 kGy
6. PPG400, 0 kGy
7. PPG400, 45 kGy
8. Dehydrated in PPG400 and Rehydrated with PBS and Ascorbate, 0 kGy
9. Dehydrated in PPG400 and Rehydrated with PBS and Ascorbate, 45 kGy

Gamma Irradiation of Porcine Heart Valve Cusps in the Presence of Various Solvents



1. Molecular Weight Markers
2. 50% DMSO, 0 kGy
3. 50% DMSO, 45 kGy
4. 50% DMSO and Ascorbate, 0 kGy
5. 50% DMSO and Ascorbate, 45 kGy

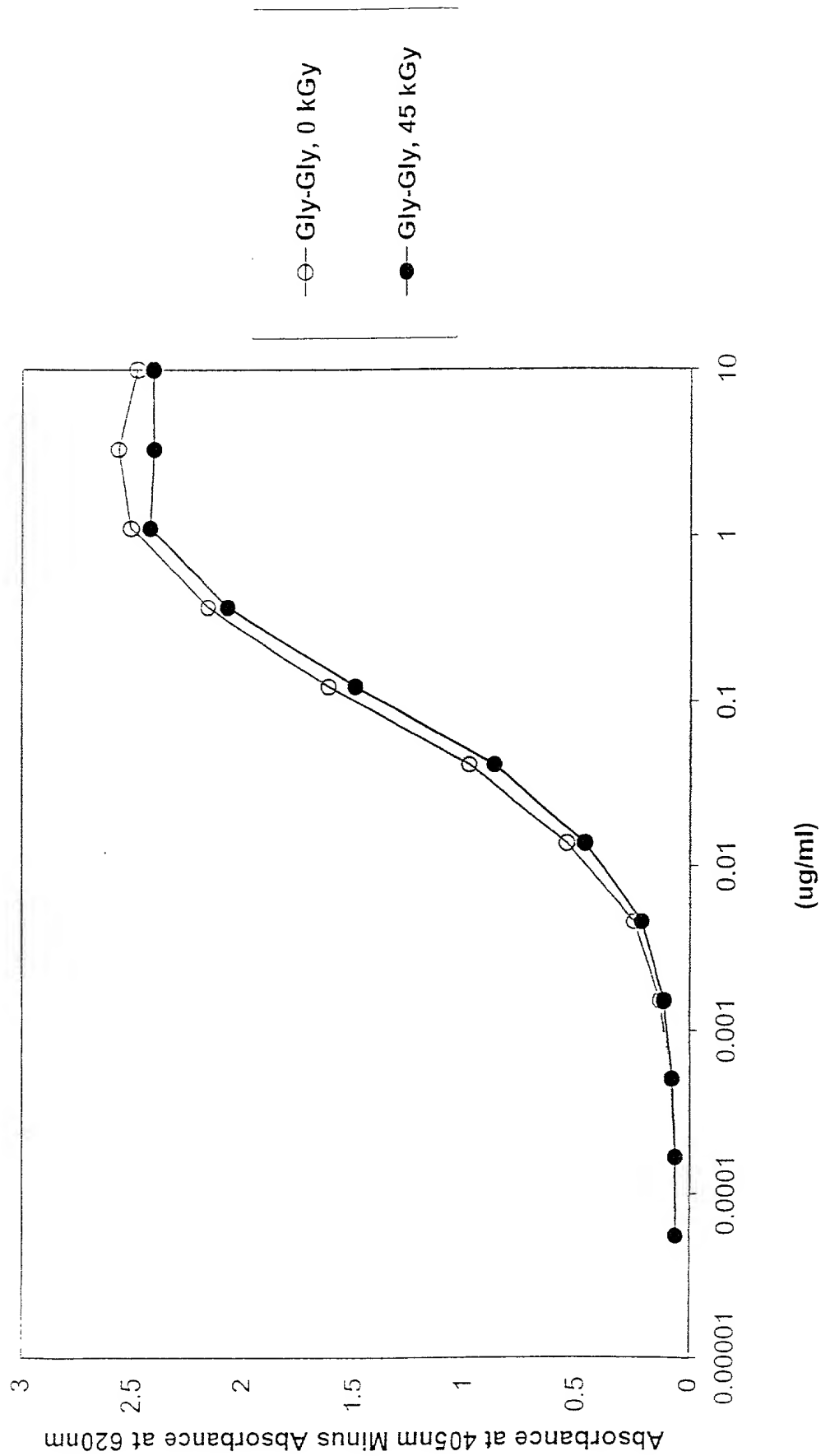
205
119
98
52.3
36.8
30.1
22
7.6

1 2 3 4 5

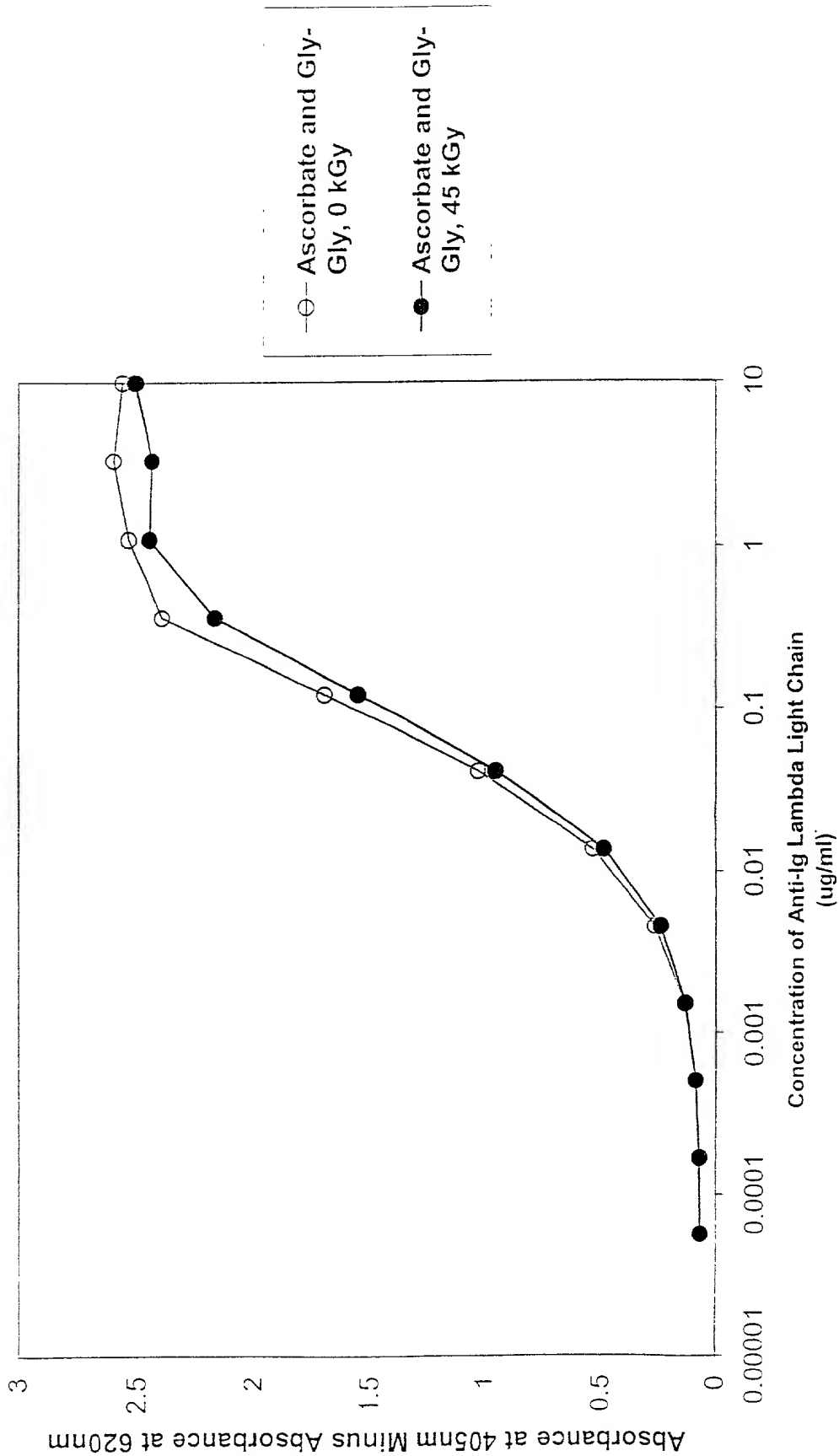
(7H)



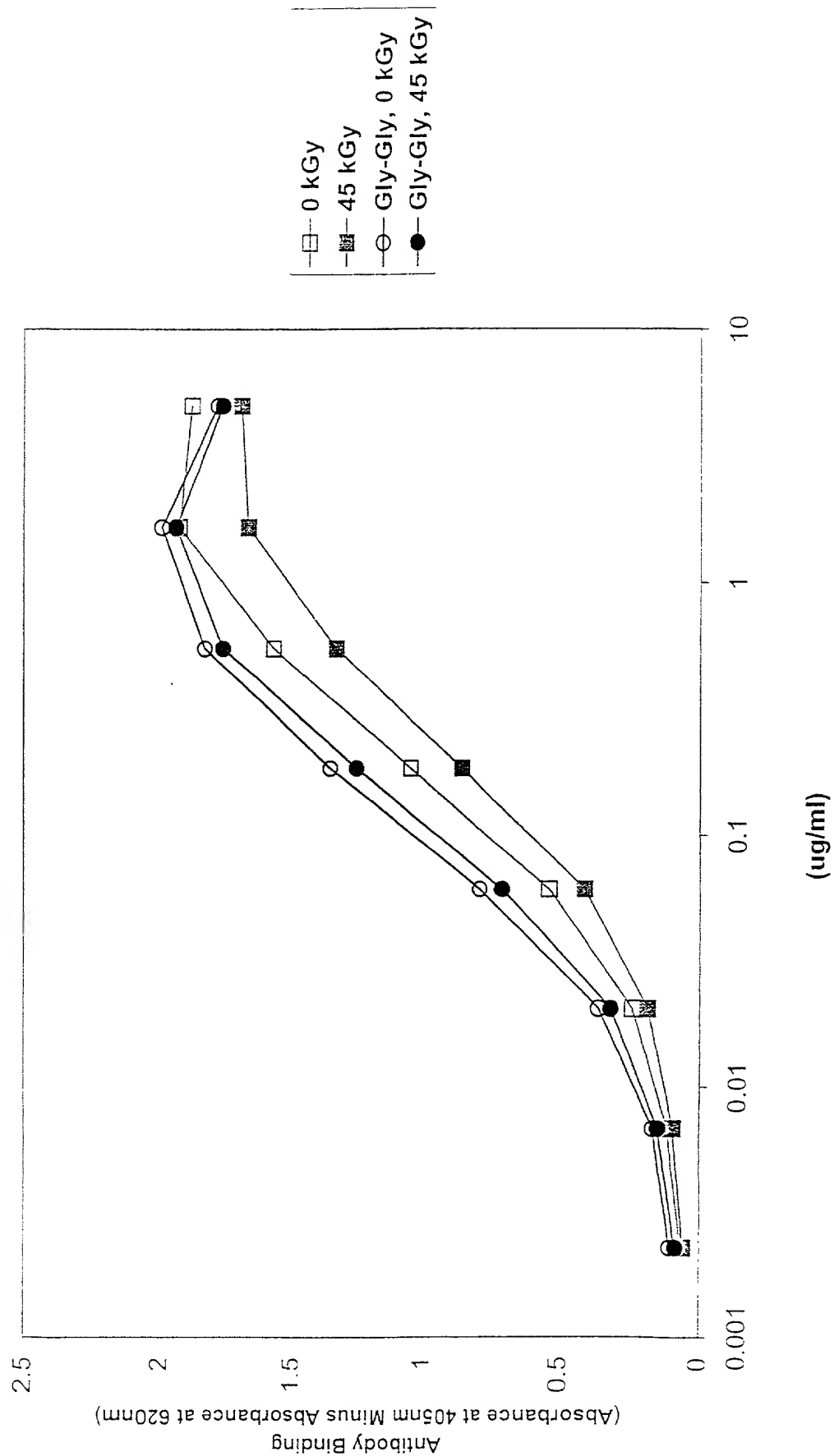
Gamma Irradiation of Freeze-Dried Anti-Human Ig, Lambda Light Chain, in the Presence or Absence of 20 mM Gly-Gly



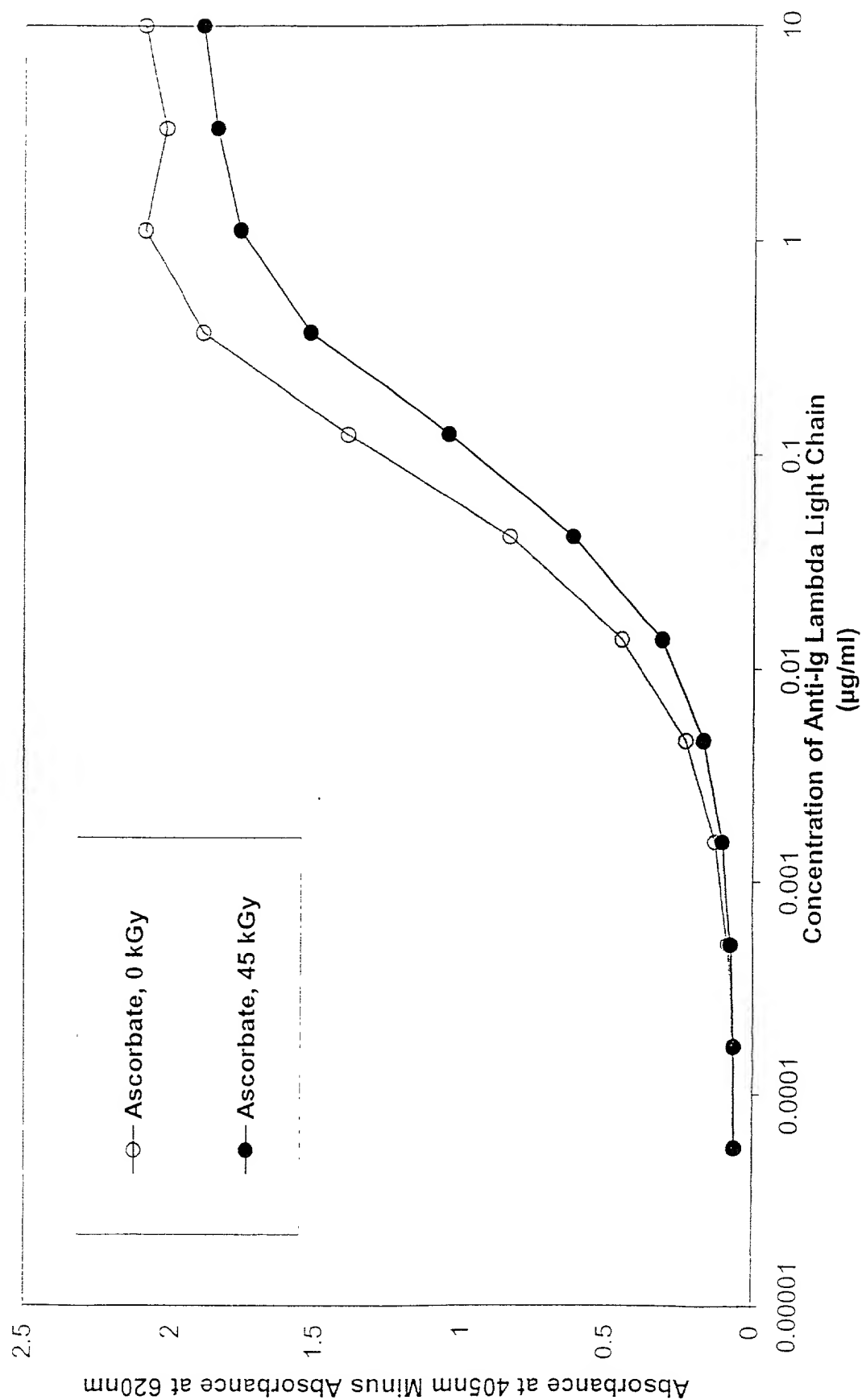
Gamma Irradiation of Freeze-Dried Anti-Human Ig, Lambda Light Chain, in the Presence or Absence of 20 mM Ascorbate and 20 mM Gly-Gly

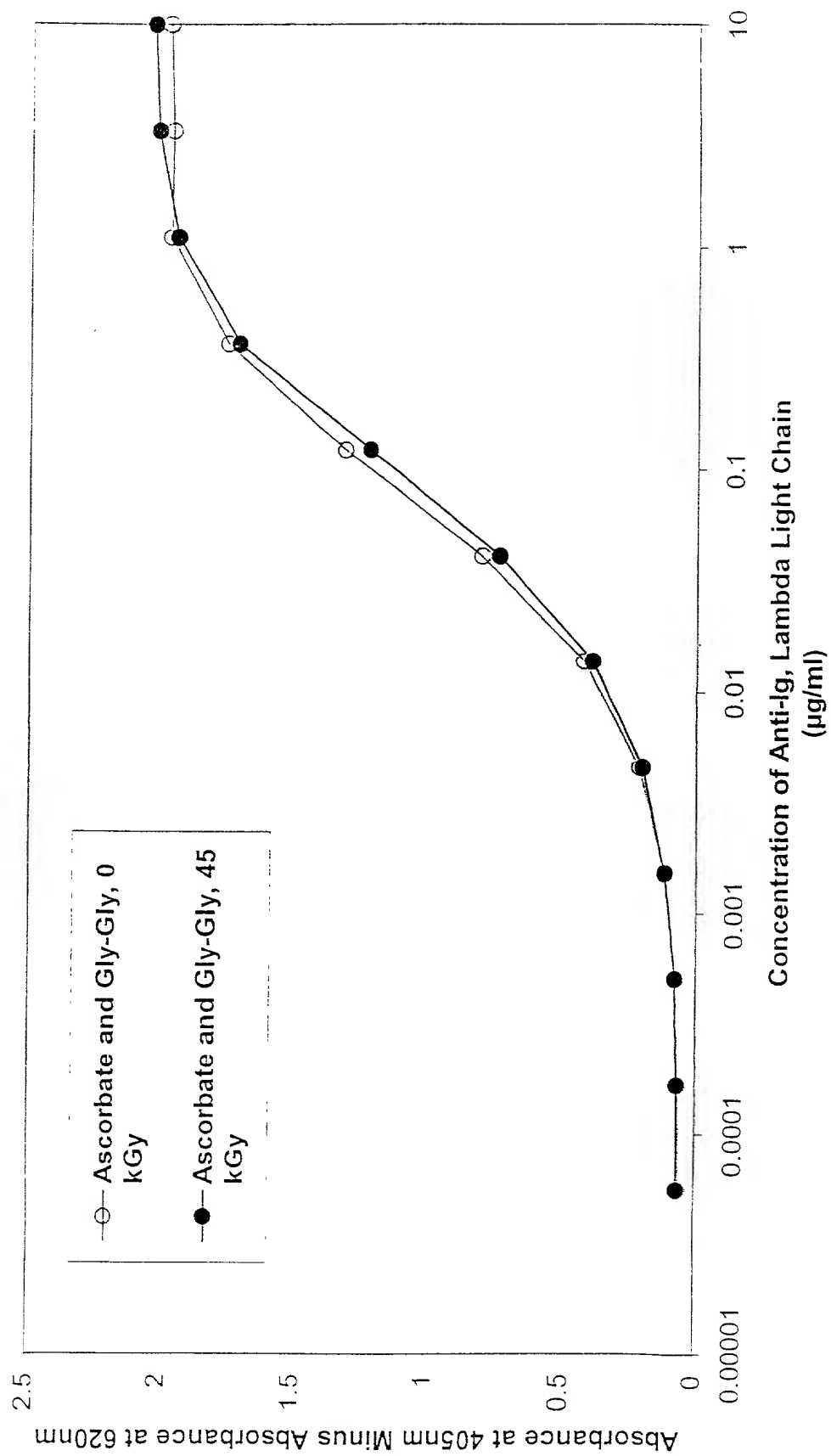


Gamma Irradiation of Freeze-Dried Anti-Insulin Monoclonal Antibody in the Presence or Absence of 20 mM Gly-Gly (and 1% BSA)

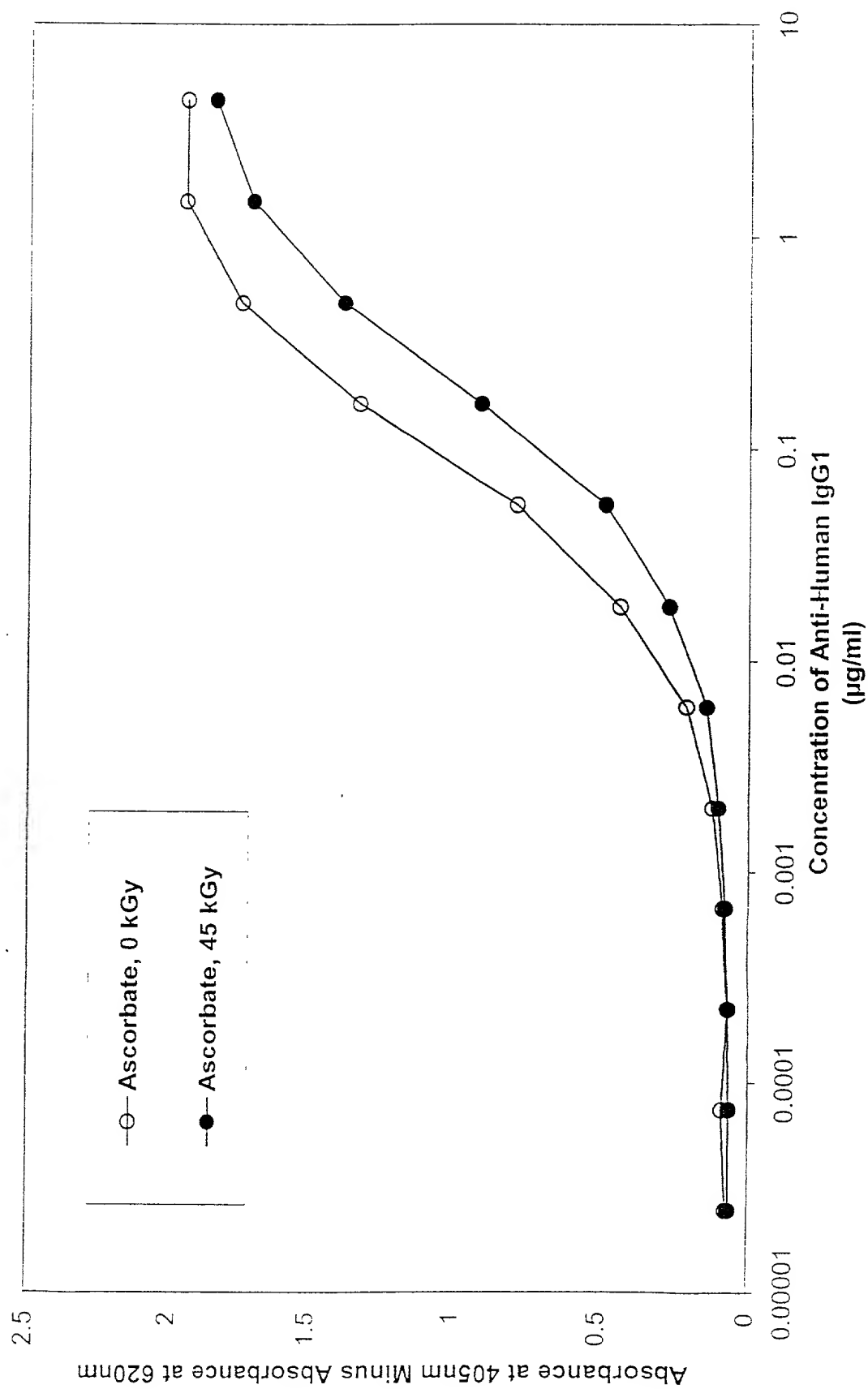


Gamma Irradiation of Liquid Anti-Human Ig, Lambda Light Chain in the Presence or Absence of 200mM Ascorbate

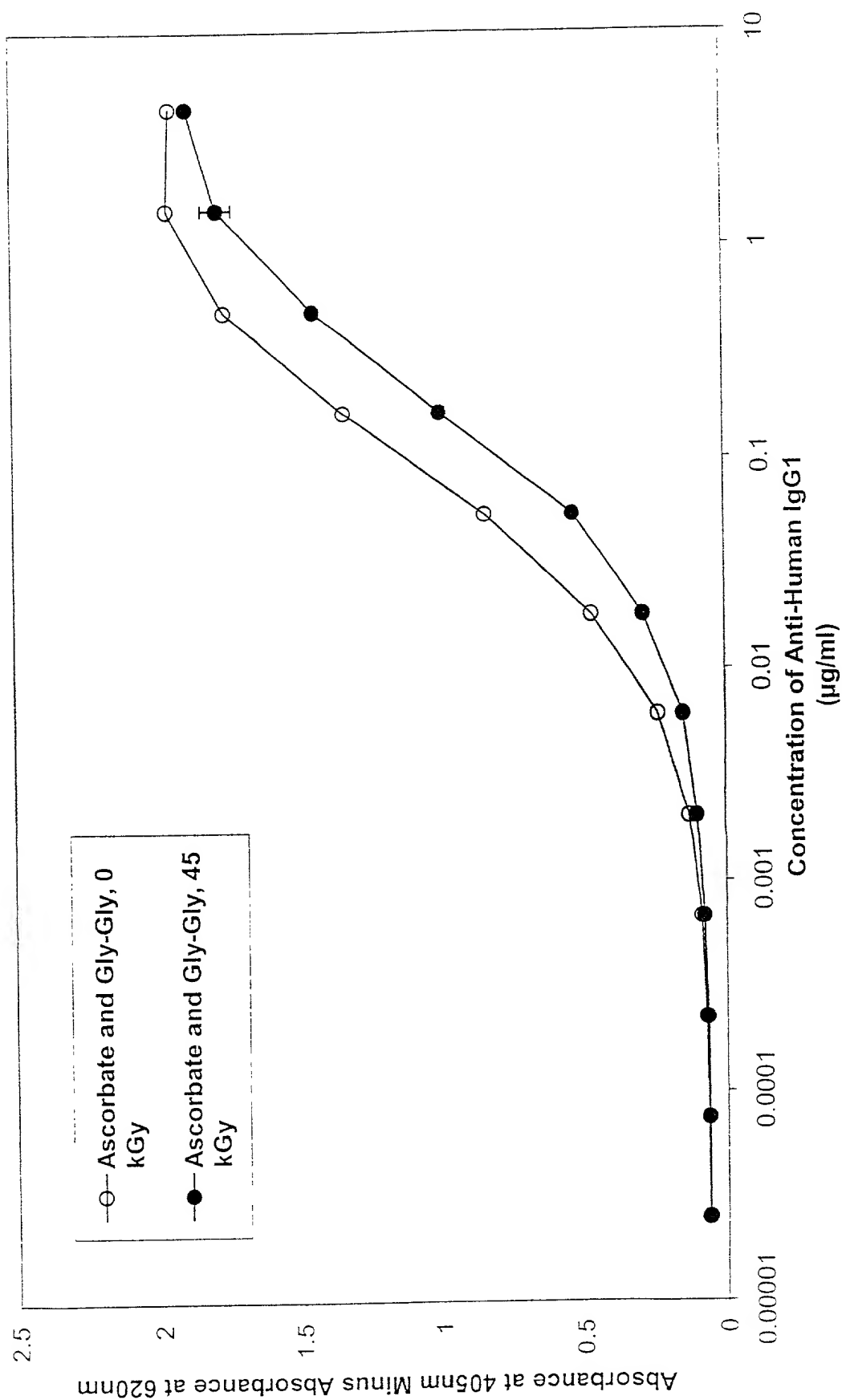




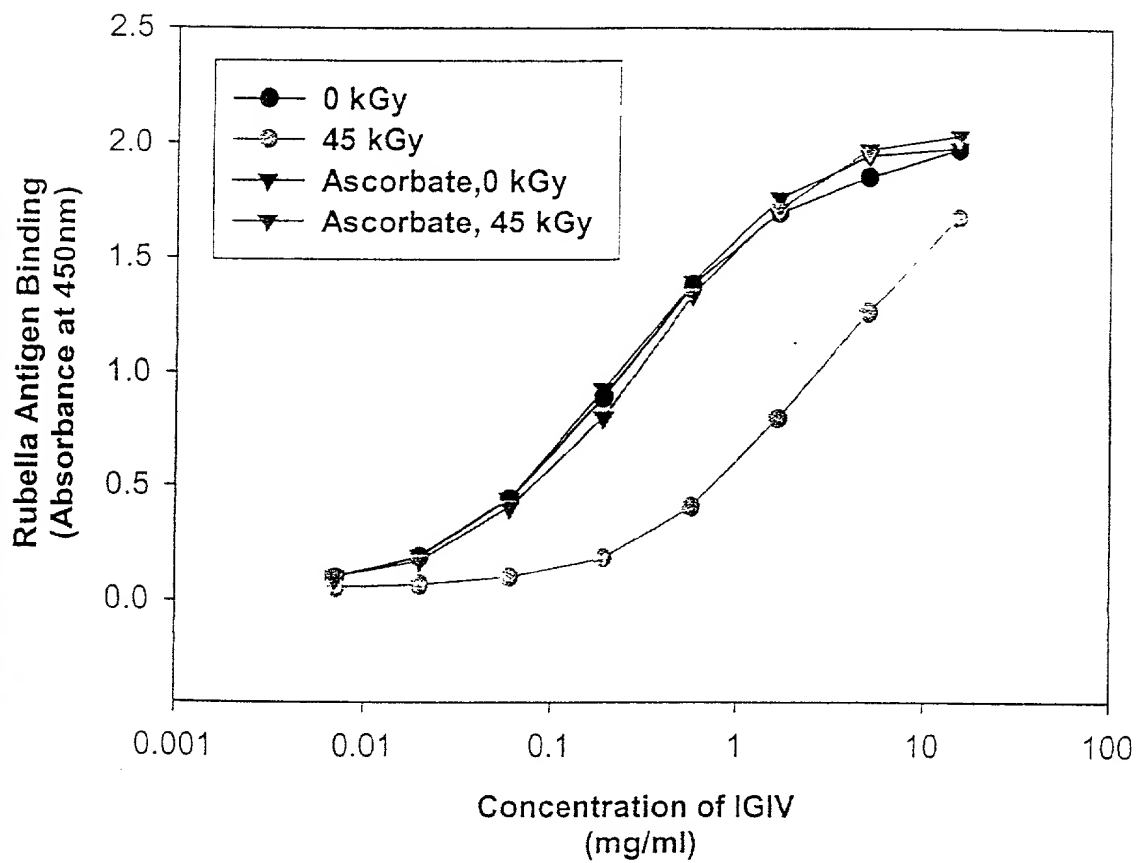
Gamma Irradiation of Liquid Anti-Human IgG1 in the Presence of 200mM Ascorbate



Gamma Irradiation of Liquid Anti-Human IgG1 in the Presence of 200mM Ascorbate and 200mM Gly-Gly

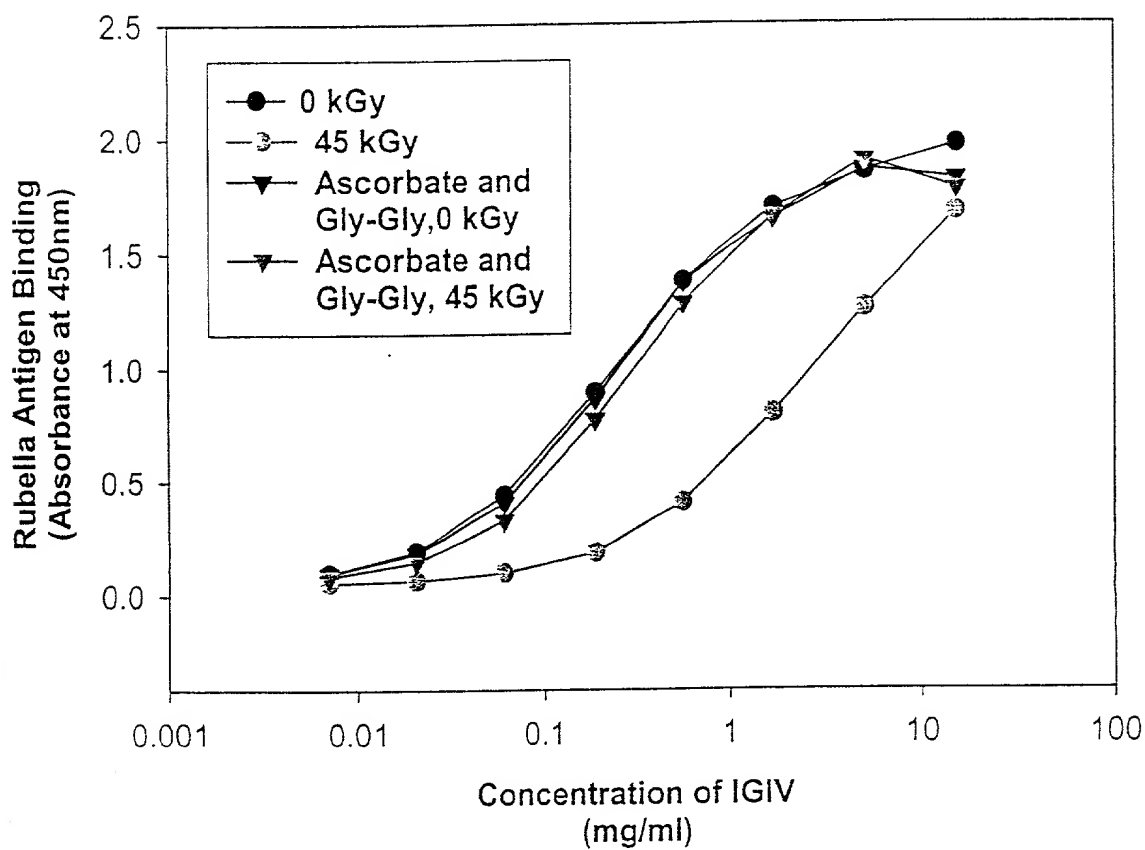


Gamma Irradiation of Liquid
IGIV in the Presence or Absence of 200 mM Ascorbate
Using Rubella IgG Assay



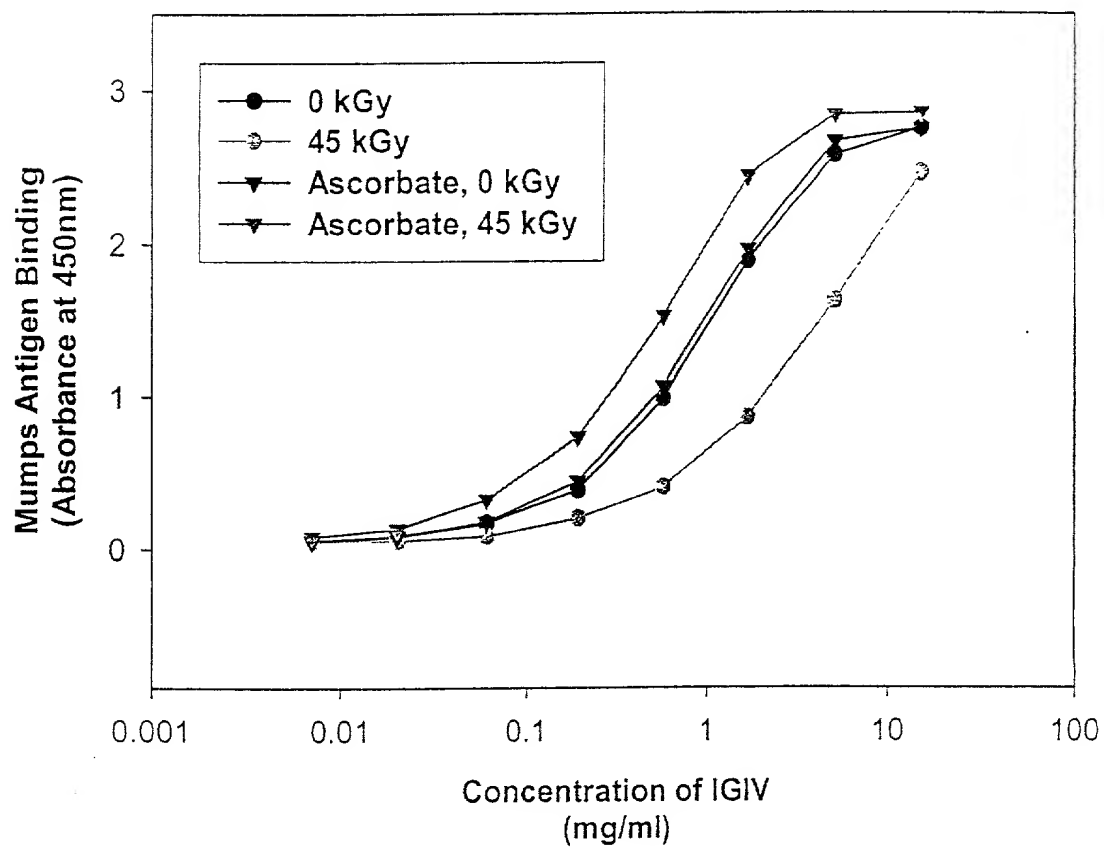
20A

Gamma Irradiation of Liquid IGIV in the Presence or Absence of 200 mM Ascorbate and 200 mM Gly-Gly Using Rubella IgG Assay



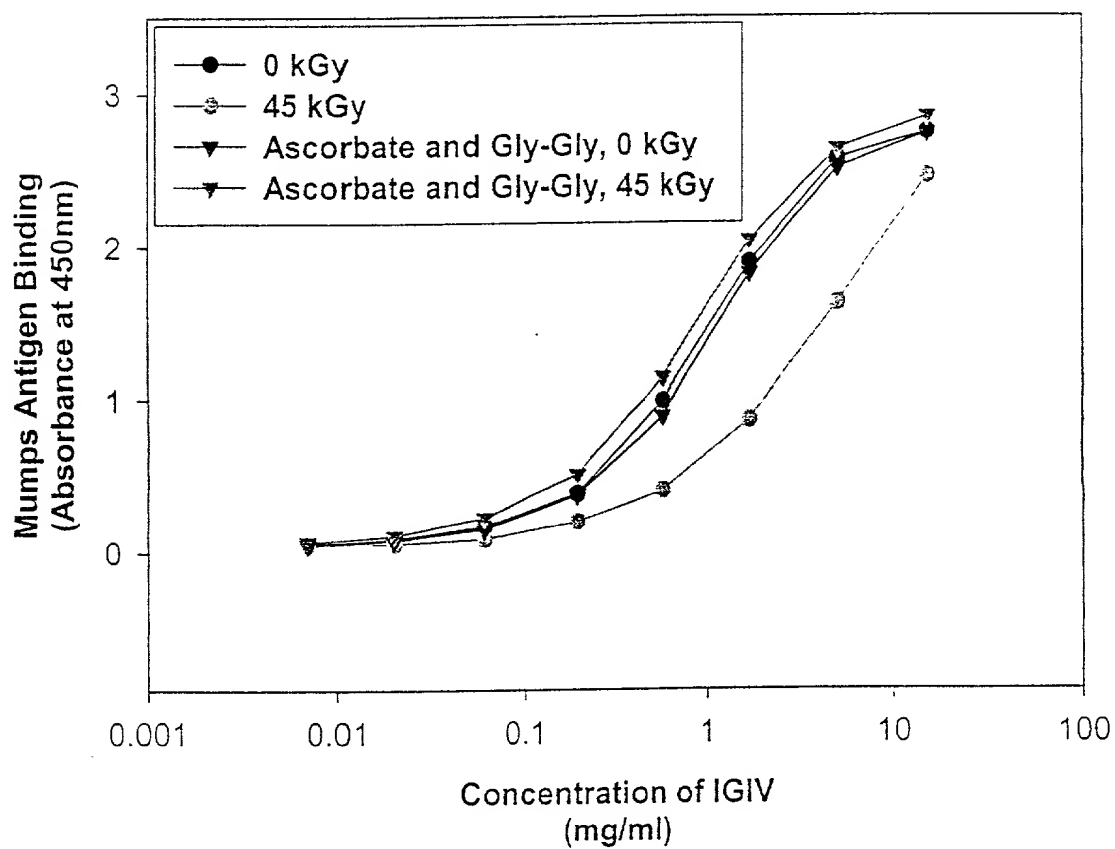
20B

Gamma Irradiation of Liquid
IGIV in the Presence or Absence of 200 mM Ascorbate
Using Mumps Assay



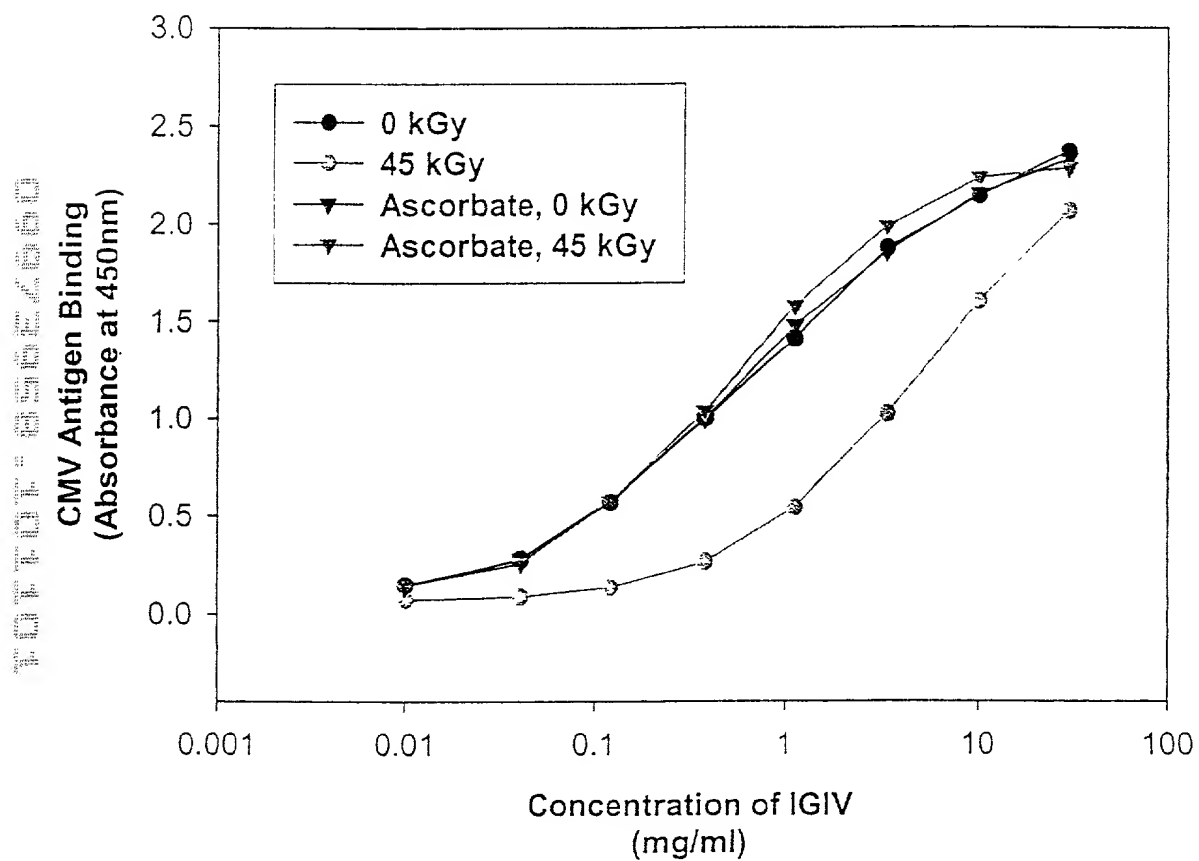
20C

Gamma Irradiation of Liquid IGIV in the Presence or Absence of 200 mM Ascorbate and 200 mM Gly-Gly Using Mumps Assay



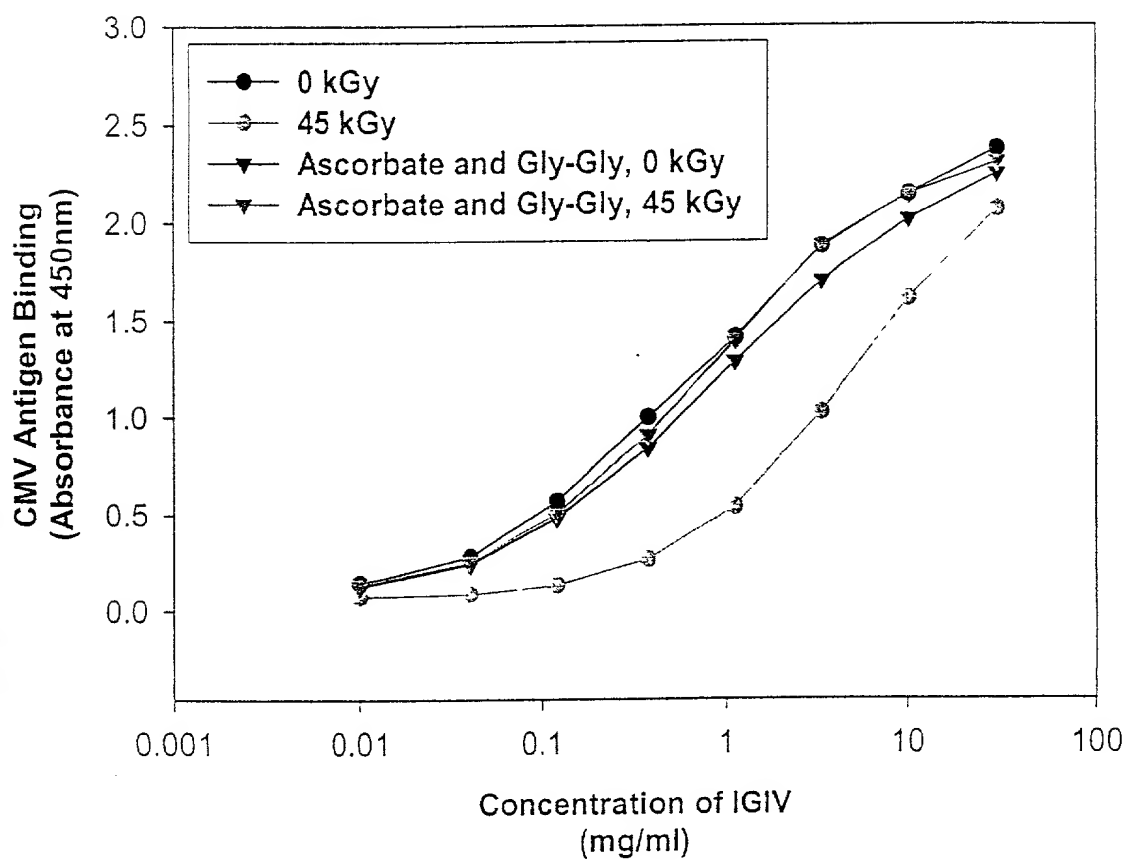
20D

Gamma Irradiation of Liquid IGIV in the Presence or Absence of 200 mM Ascorbate Using CMV Assay



20E

Gamma Irradiation of Liquid IGIV in the Presence or Absence of 200 mM Ascorbate and 200 mM Gly-Gly Using CMV Assay

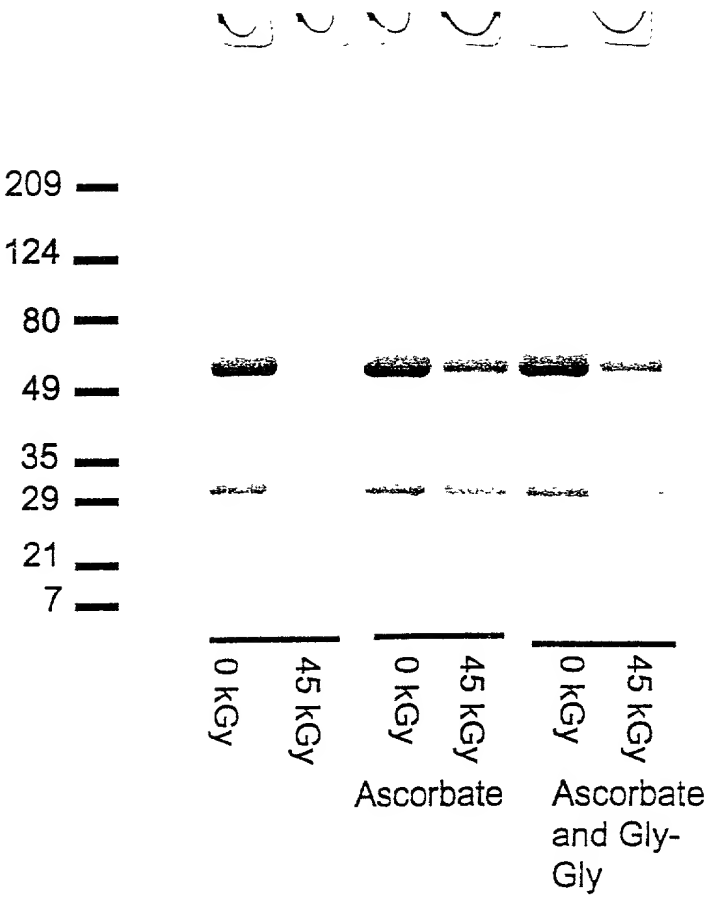


20F

SDS-PAGE of

Liquid IGIV

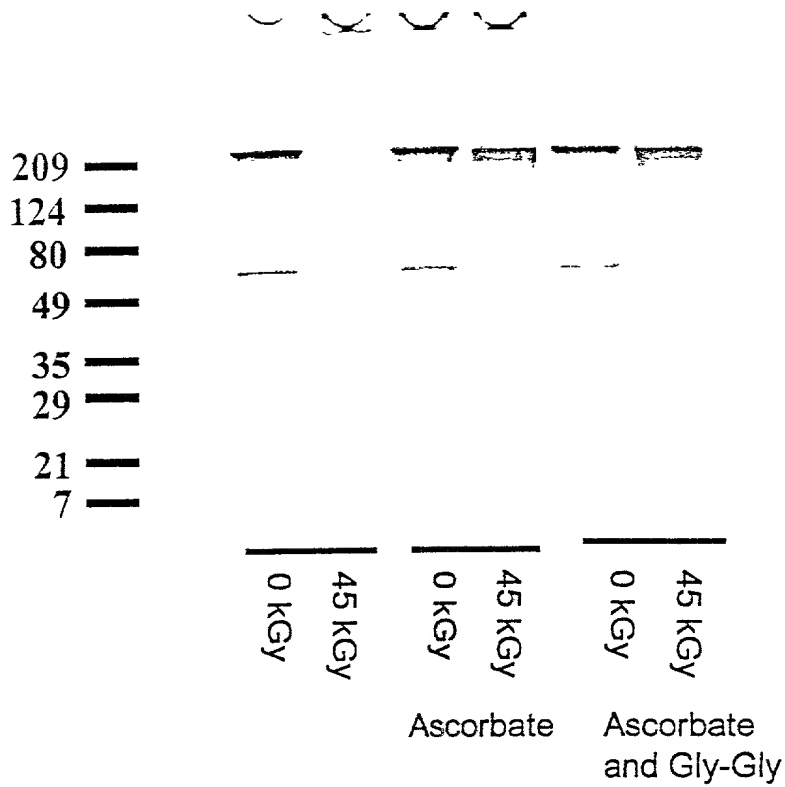
Liquid IGIV, Reduced 5-15%



206

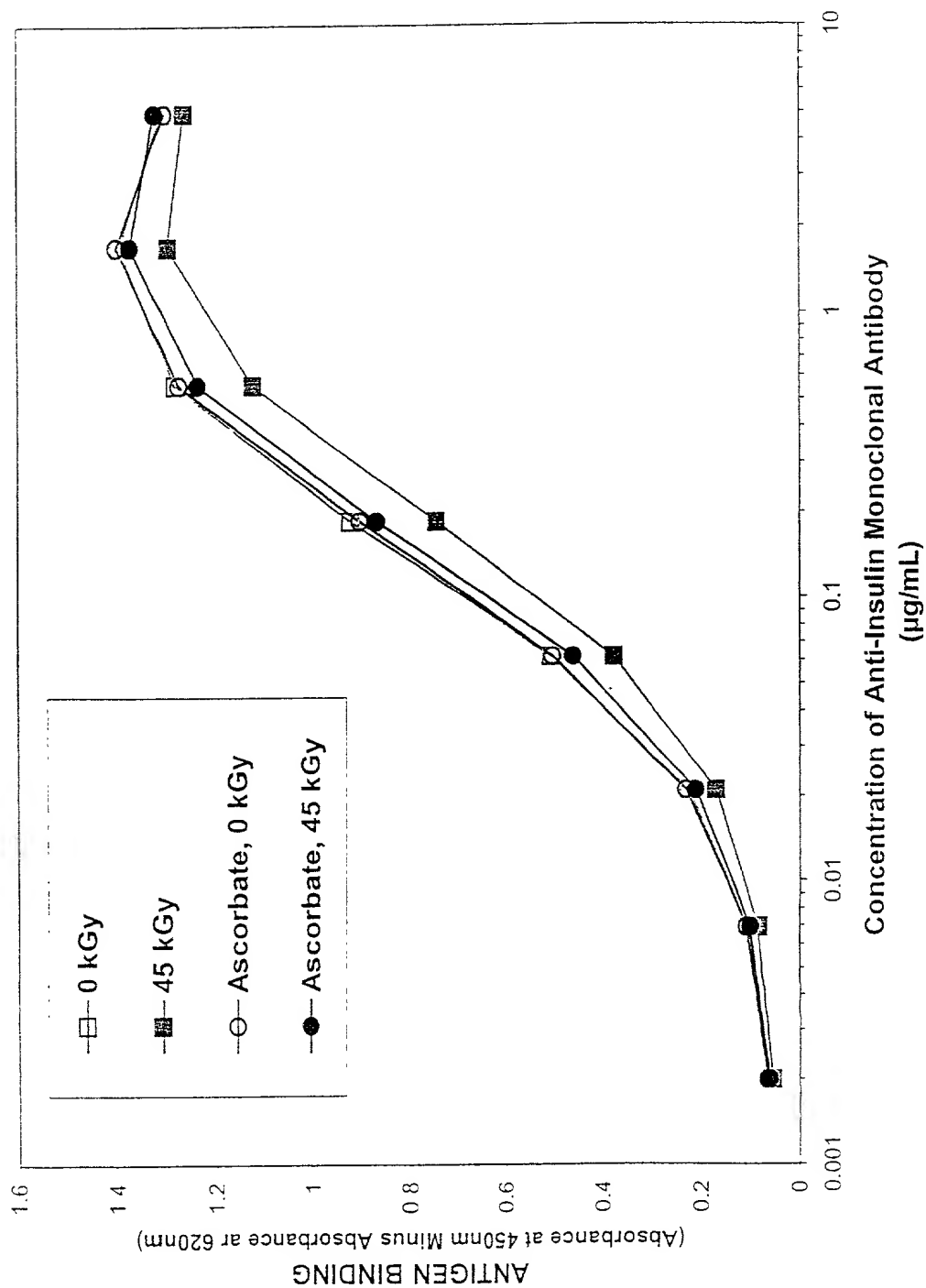
SDS-PAGE of Liquid IGIV

Liquid IGIV, Non-Reduced 5-15%

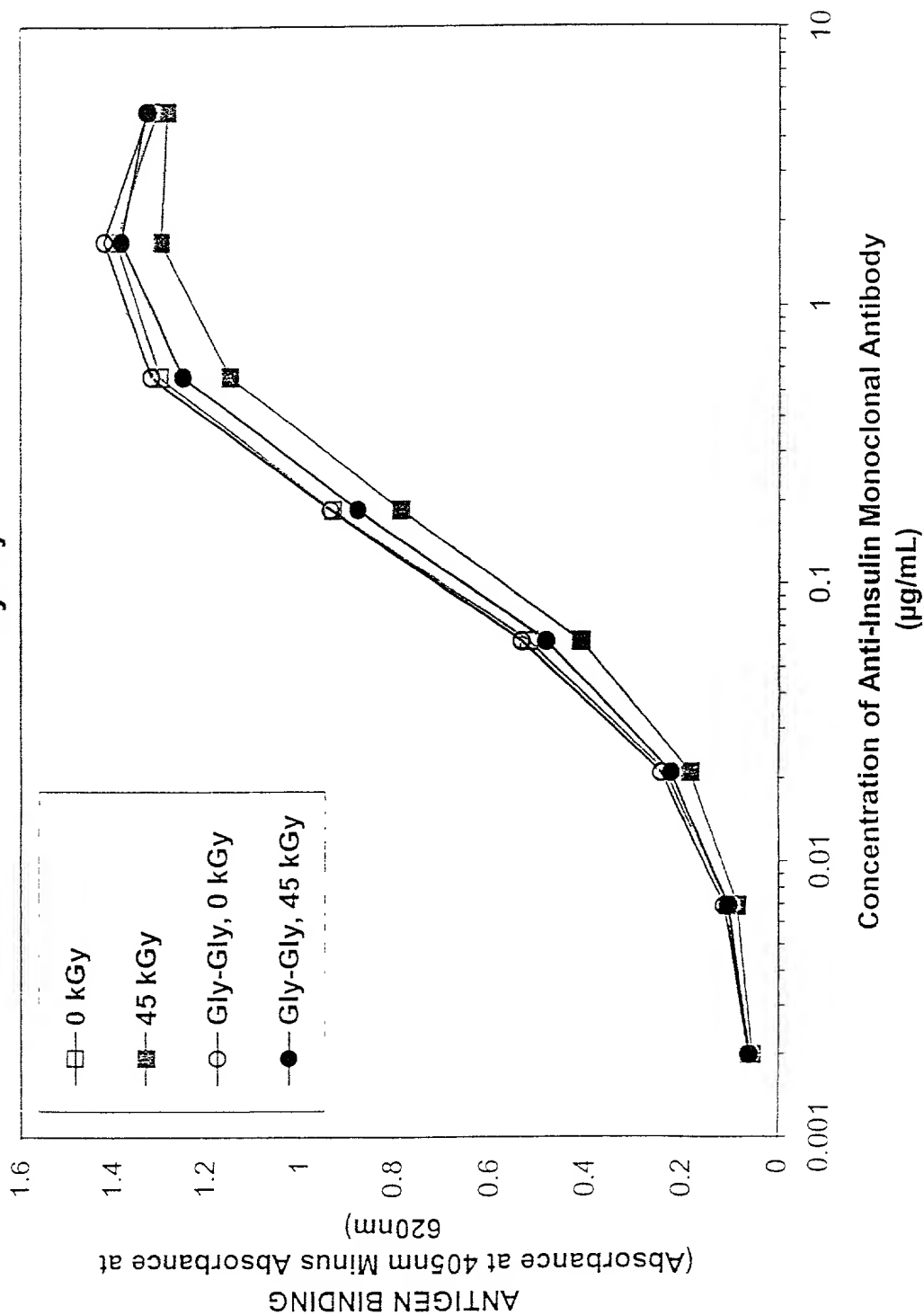


20H

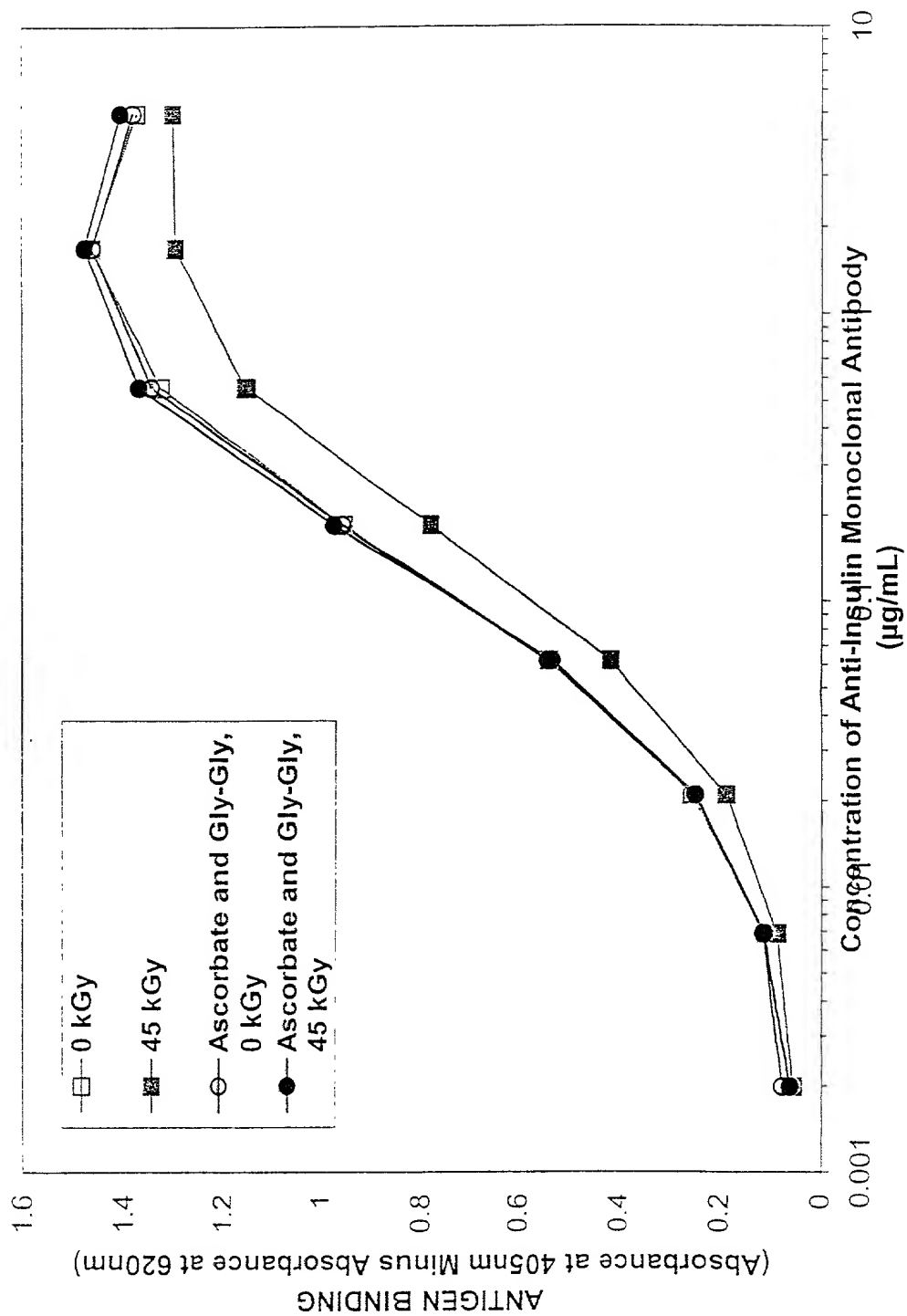
Gamma Irradiation of Freeze-Dried Anti-Insulin Monoclonal Antibody at a High Dose Rate (30 kGy/h) in the Presence or Absence of 20 mM Ascorbate



Gamma Irradiation of Freeze-Dried Anti-Insulin Monoclonal Antibody at a High Dose Rate (30 kGy/h) in the Presence or Absence of 20 mM Gly-Gly



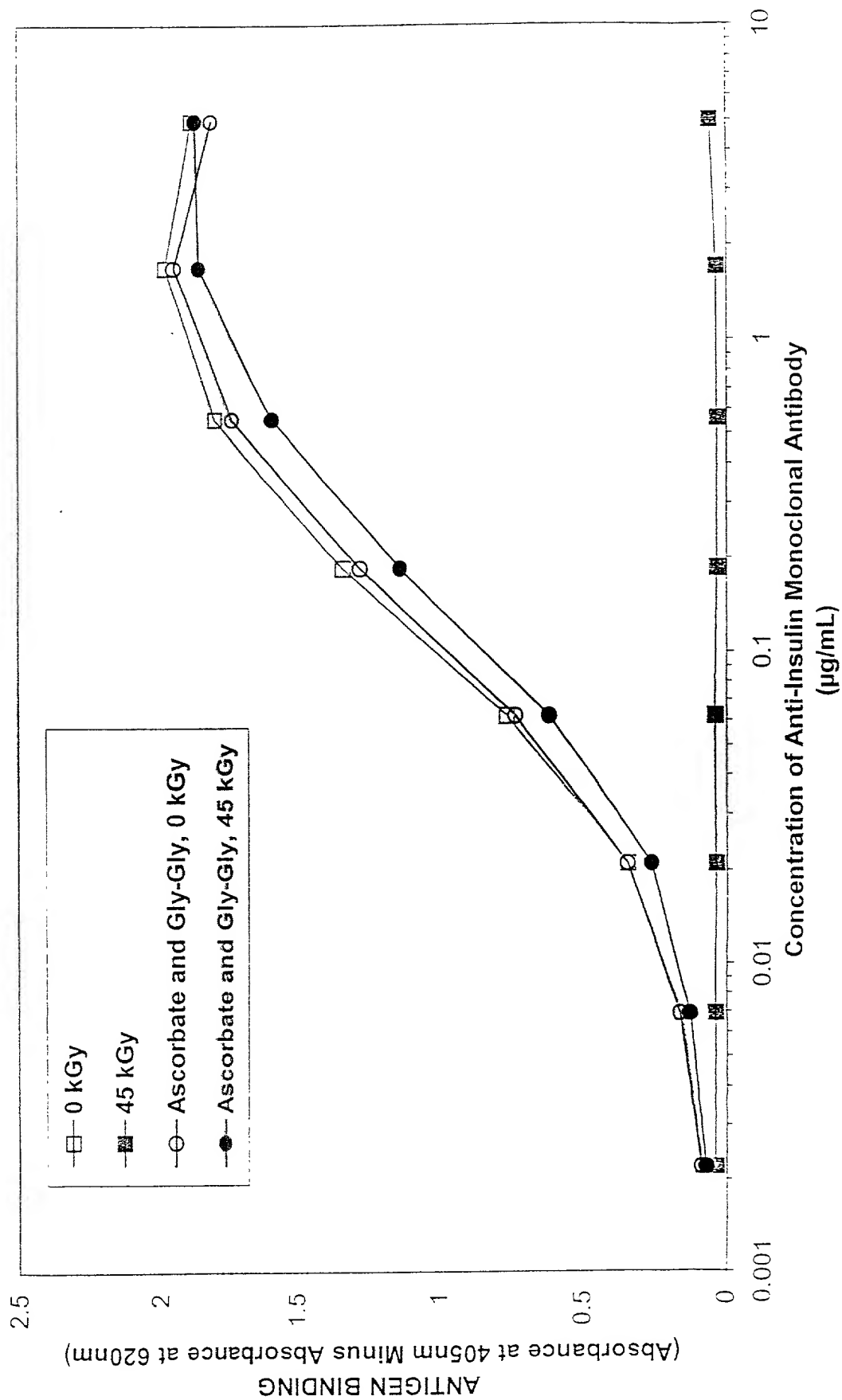
Gamma Irradiation of Freeze-Dried Anti-Insulin Monoclonal Antibody at a High Dose Rate 30 kGy/h in the Presence or Absence of 20 mM Ascorbate and 20 mM Gly-Gly



21C



Gamma Irradiation of Anti-Insulin Monoclonal Antibody in the Presence or Absence of 200 mM Ascorbate and 200 mM Gly-Gly



223

SDS-PAGE for a Glycosidase

Nonreduced

Reduced

97
66
45

30

20

14

97
66
45

30

20

14

5.4 kGy/hr, 45 kGy
1.7 kGy/hr, 45 kGy
0 kGy

5.4 kGy/hr, 45 kGy
1.7 kGy/hr, 45 kGy
0 kGy

5.4 kGy/hr, 45 kGy
1.7 kGy/hr, 45 kGy
0 kGy

5.4 kGy/hr, 45 kGy
1.7 kGy/hr, 45 kGy
0 kGy

5.4 kGy/hr, 45 kGy
1.7 kGy/hr, 45 kGy
0 kGy

5.4 kGy/hr, 45 kGy
1.7 kGy/hr, 45 kGy
0 kGy

Ascorbate
and Gly-Gly

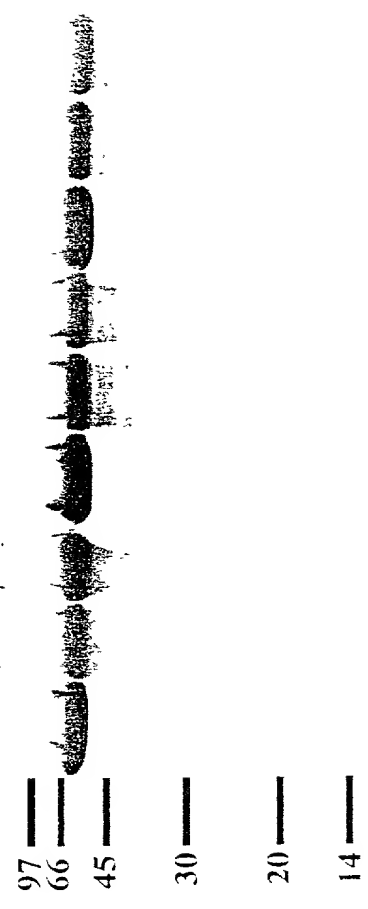
Ascorbate

Ascorbate
and Gly-Gly

23A

SDS-PAGE for a Sulfatase

Reduced

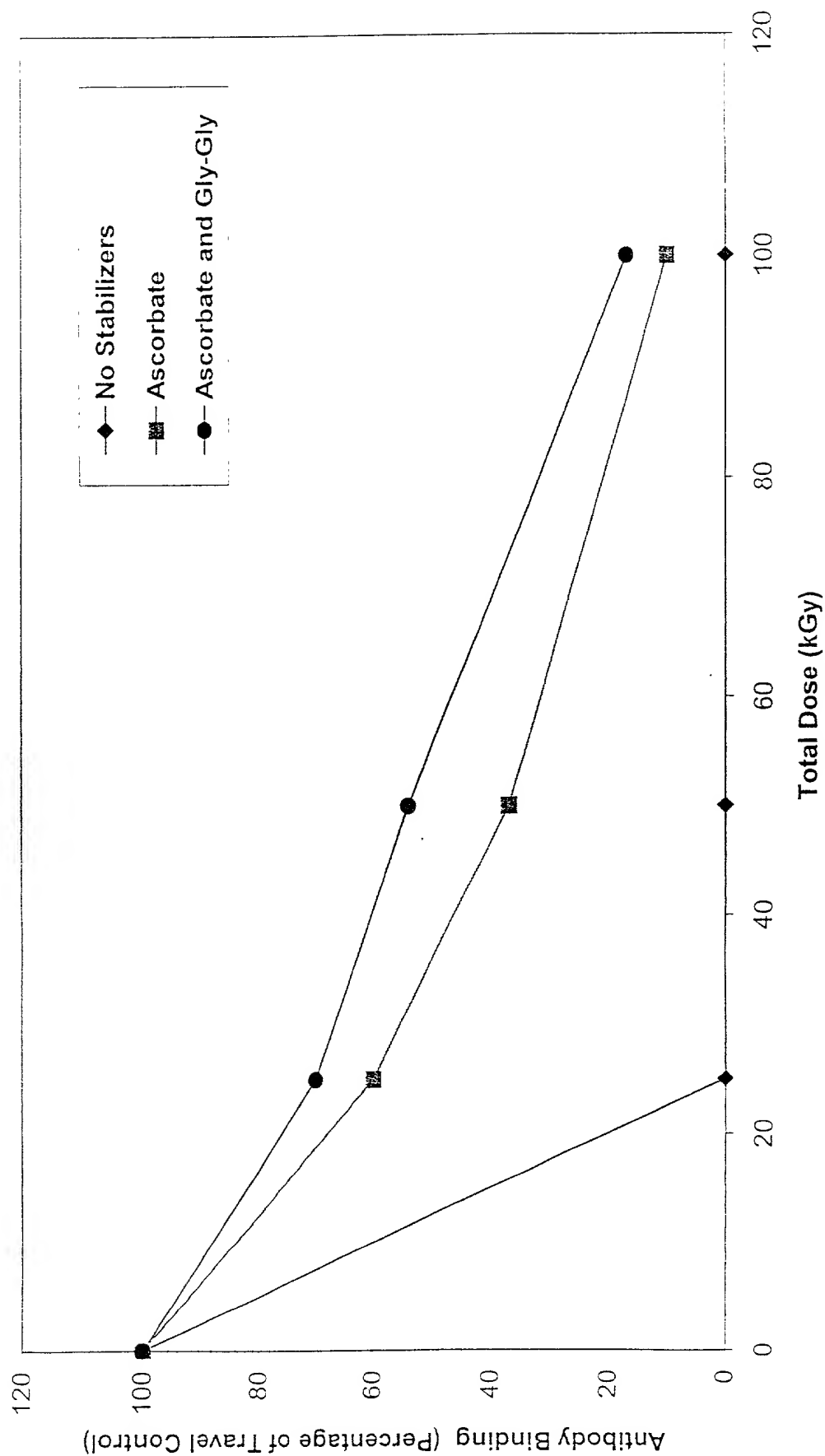


5.4 kGy/hr, 45 kGy	Ascorbate and Gly-Gly
1.7 kGy/hr, 445 kGy	
0 kGy	
5.4 kGy/hr, 45 kGy	Ascorbate
1.7 kGy/hr, 45 kGy	
0 kGy	
5.4 kGy/hr, 45 kGy	
1.7 kGy/hr, 45 kGy	
0 kGy	

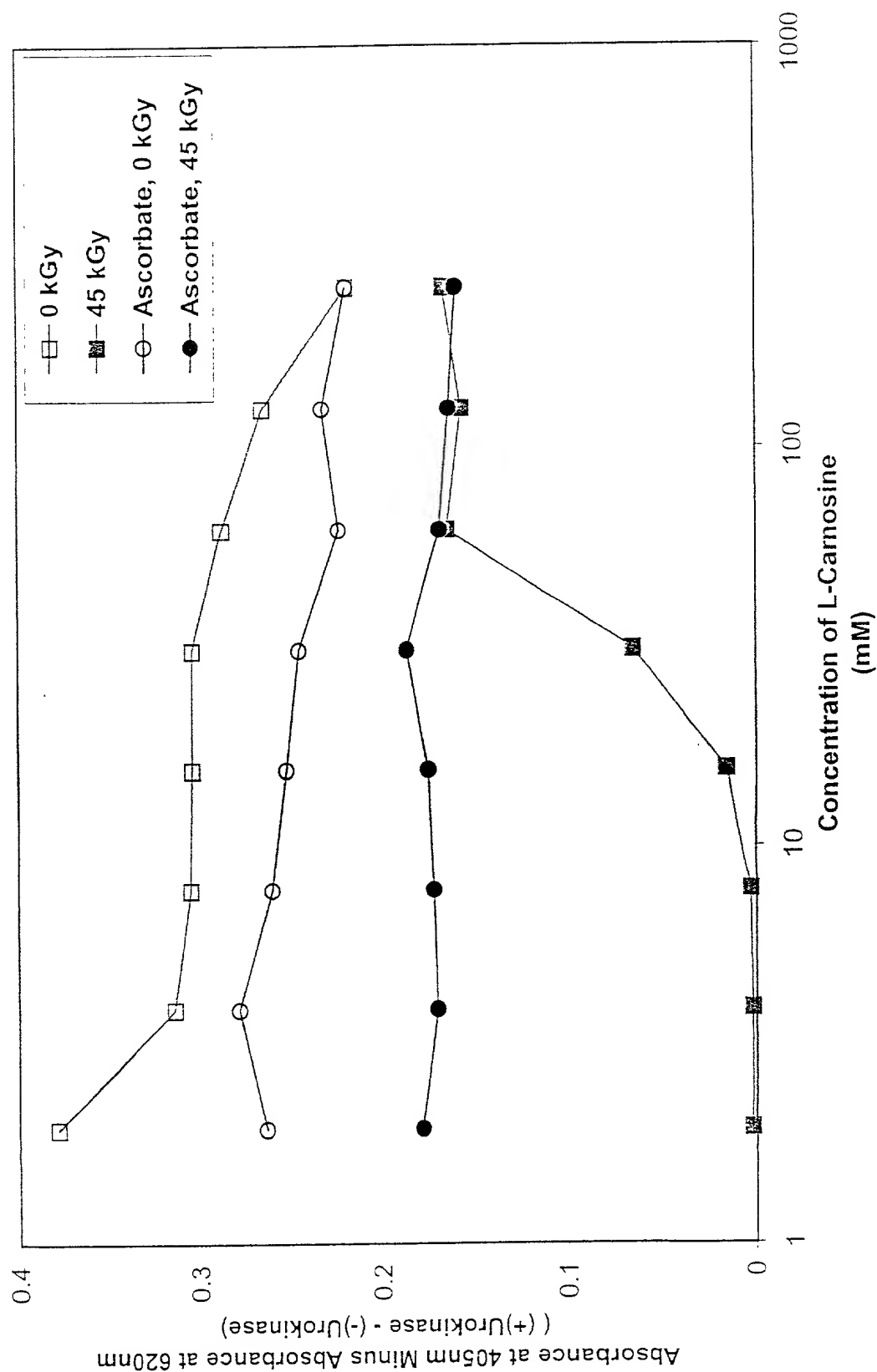
23B



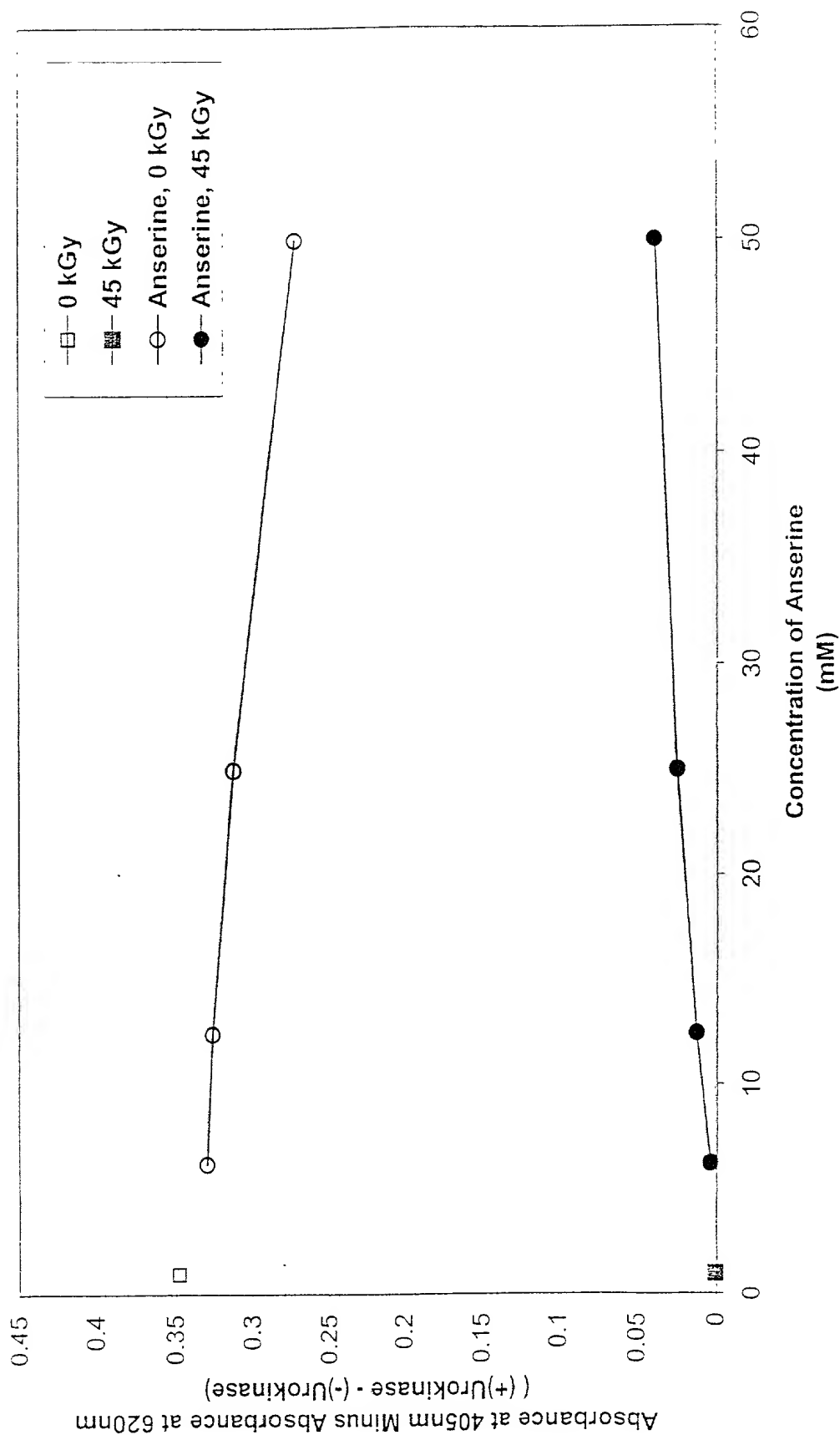
Gamma Irradiation of Liquid Anti-Insulin Monoclonal Antibody in the Presence or Absence of 200 mM Ascorbate Alone or in Combination With 200 mM Gly-Gly



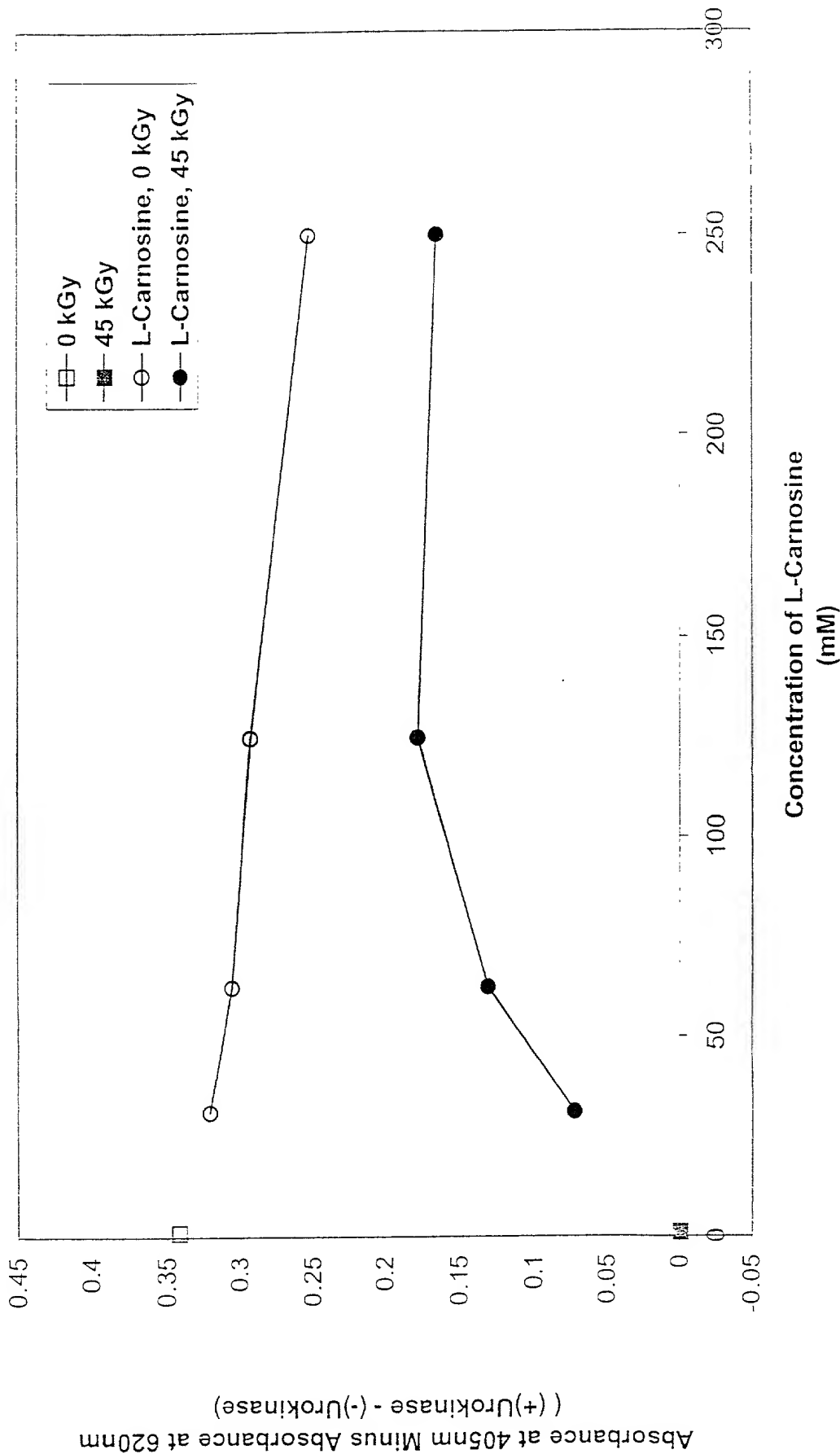
Gamma Irradiation of Liquid Urokinase, With L-Carnosine, at 45 kGy in the Presence or Absence of 50mM Ascorbate



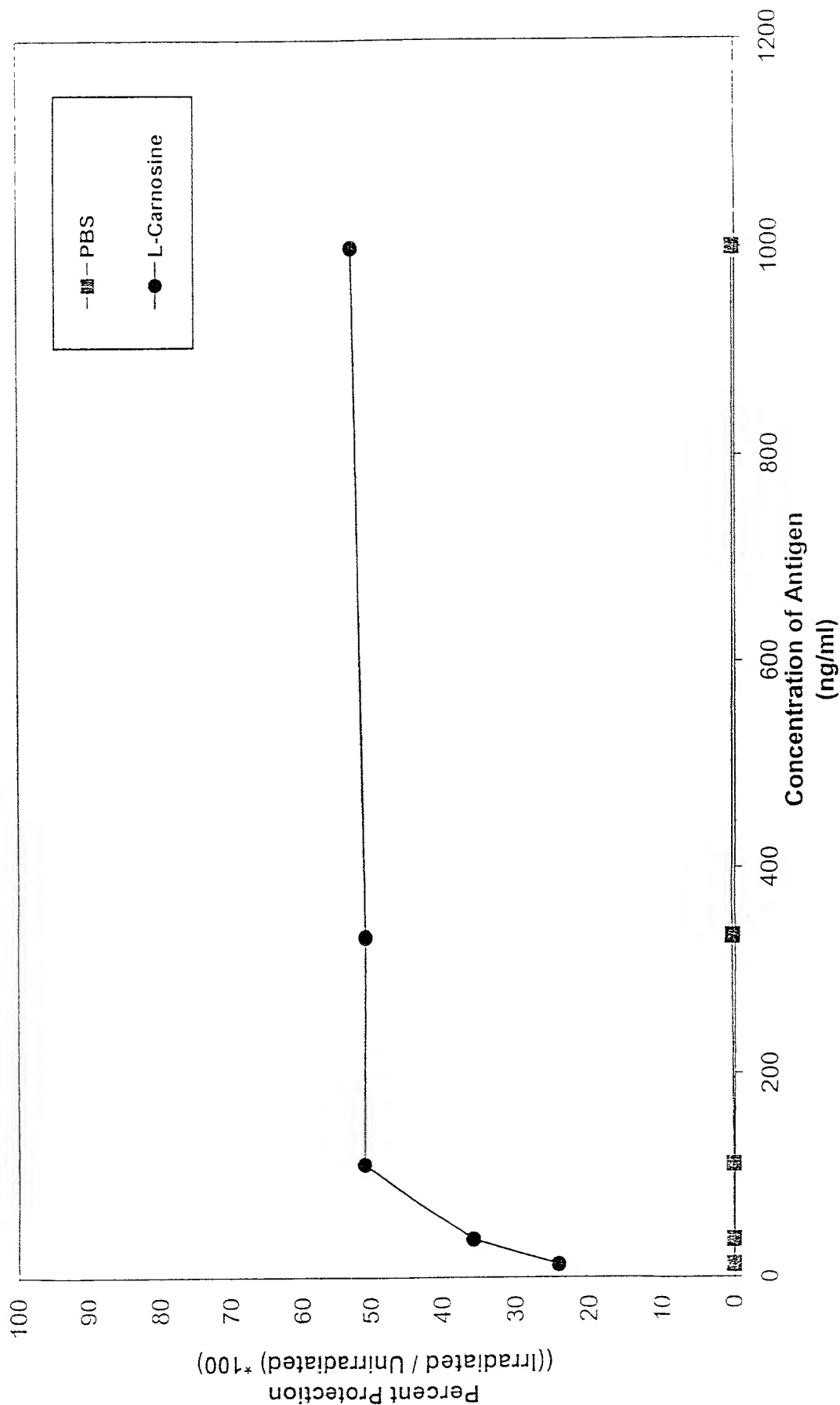
Gamma Irradiation of Liquid Urokinase in the Presence or Absence of Anserine



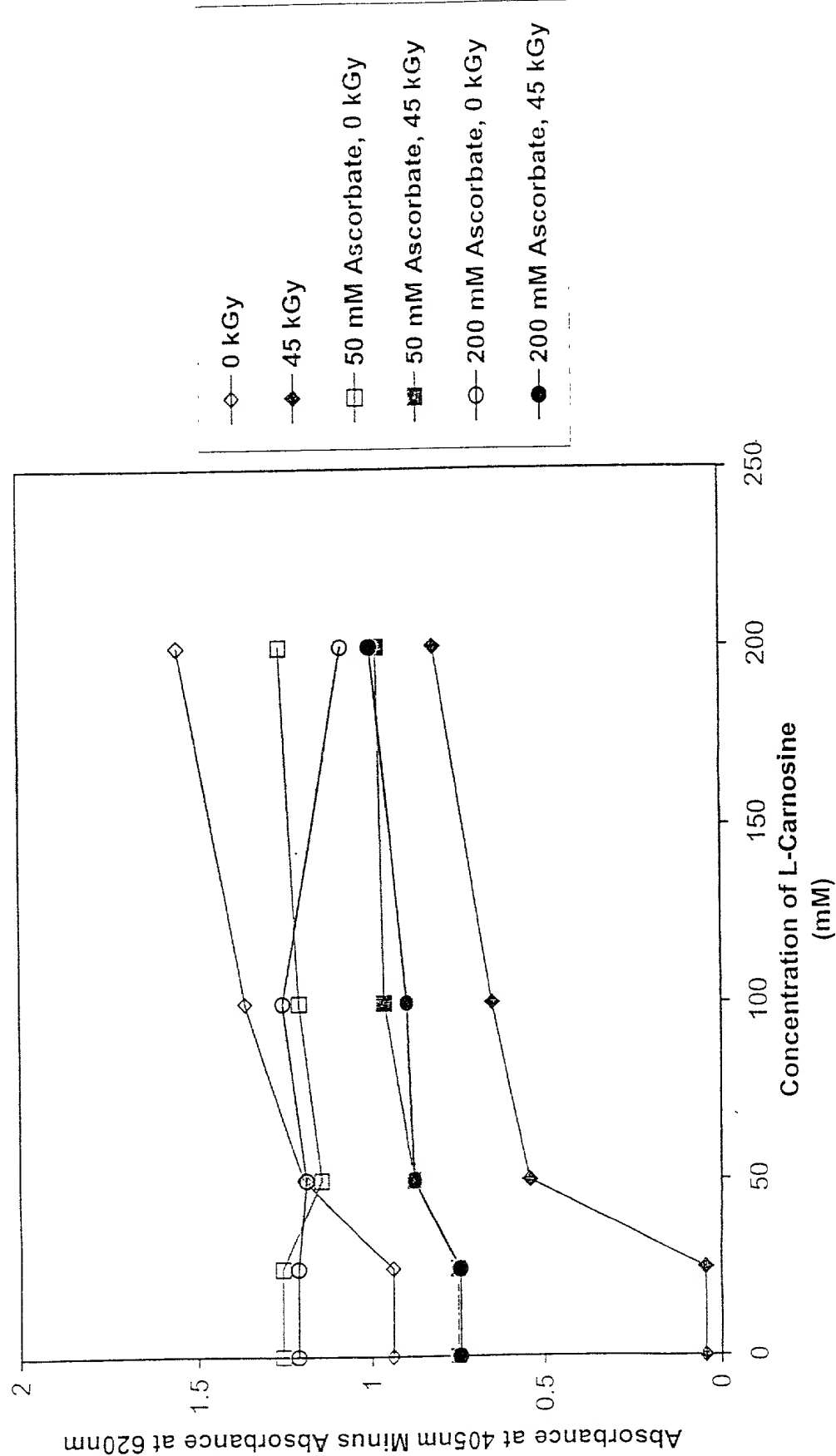
Gamma Irradiation of Liquid Urokinase in the Presence or Absence of L-Carnosine



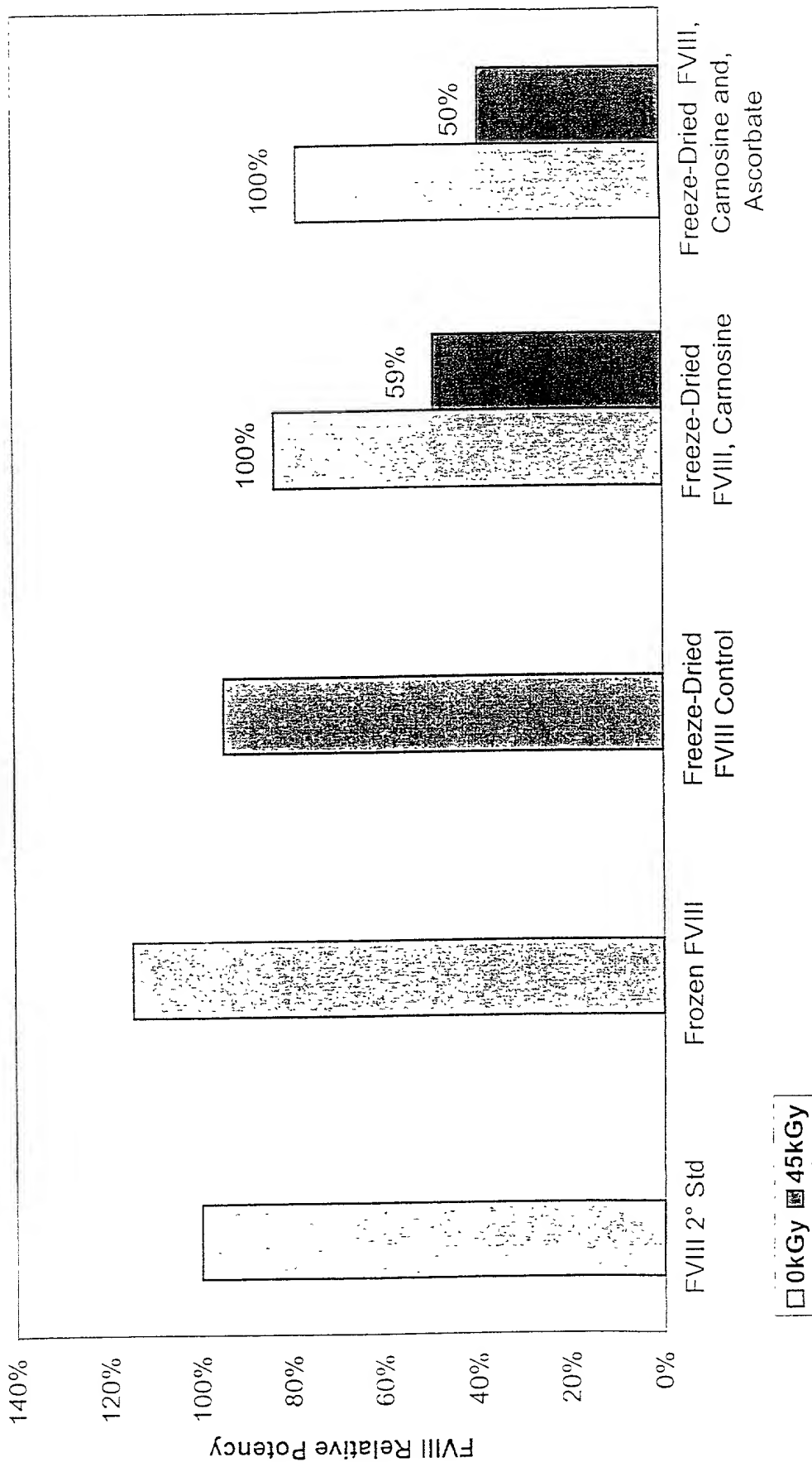
Gamma Irradiation of Immobilized Anti-Insulin Monoclonal Antibody, to 45 kGy, in the Presence or Absence of 100 mM L-Carnosine



Gamma Irradiation of Immobilized Monoclonal Antibody in the Presence or
Absence of L-Carnosine and Ascorbate

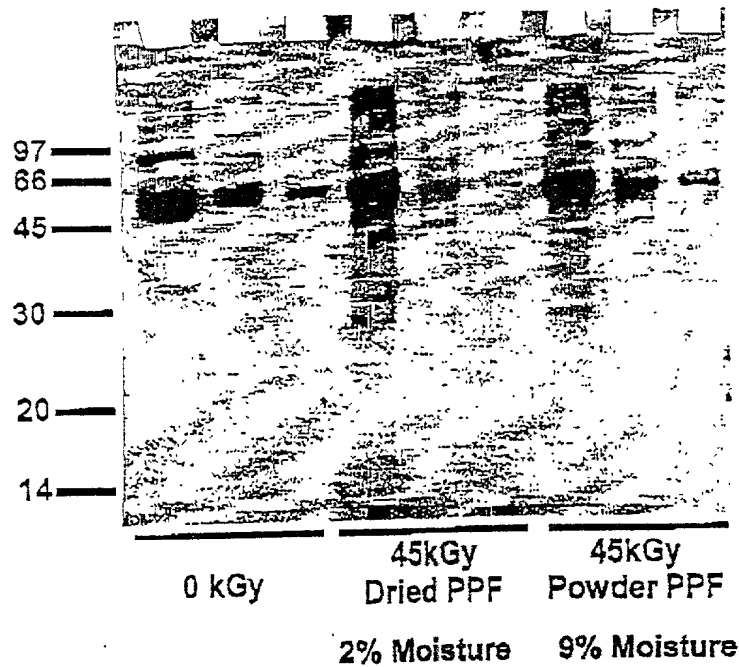


Gamma Irradiation of Freeze-Dried FVIII in the Presence or Absence of L-Carnosine Alone or in Combination with Ascorbate

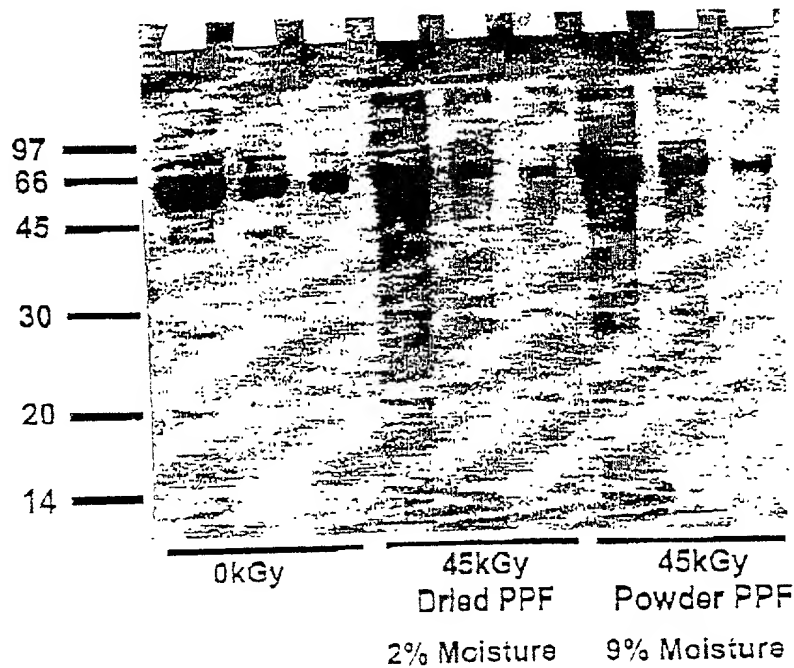


Gamma Irradiation of Dried and Powder PPF

Nonreduced, 12.5%

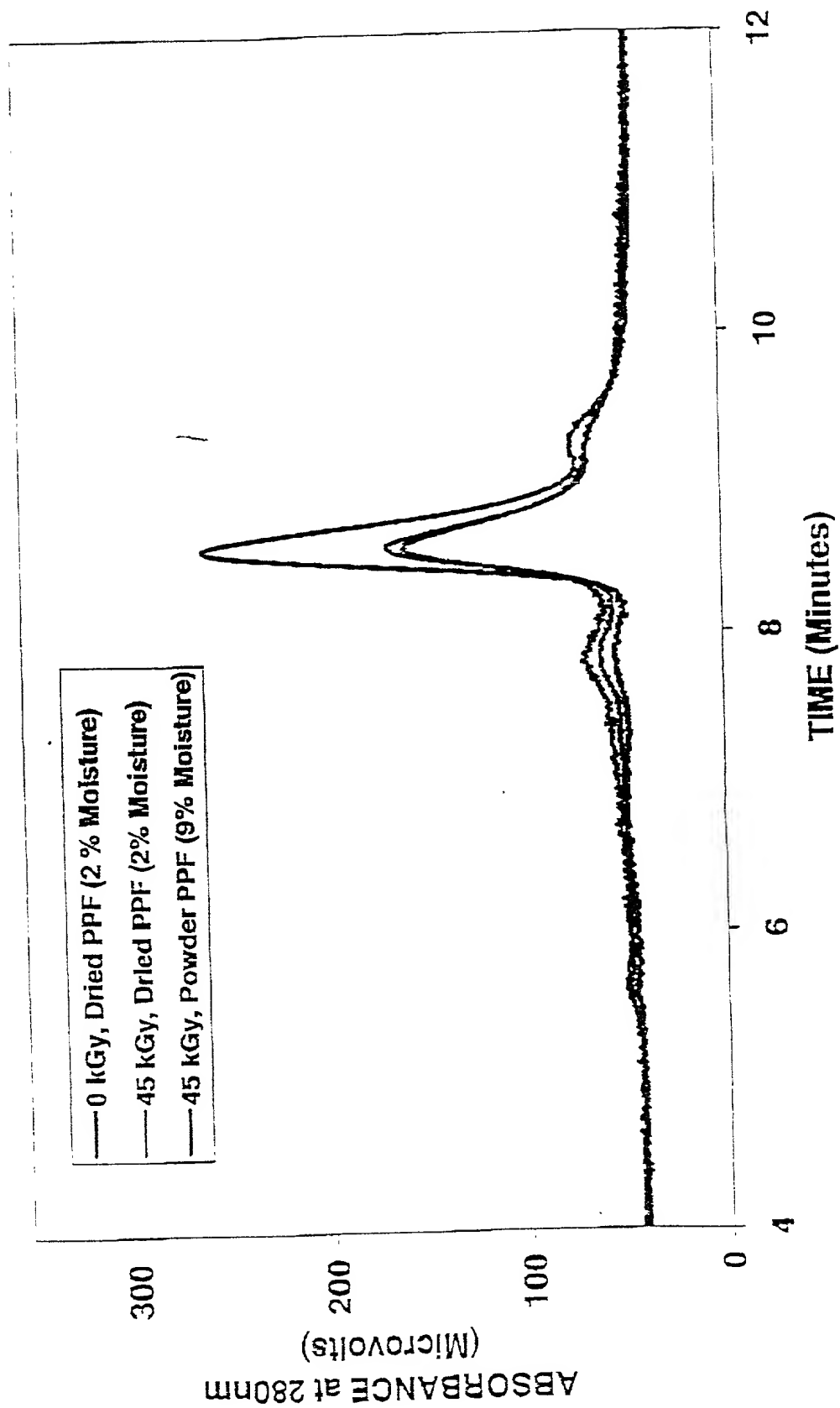


Reduced, 12.5%



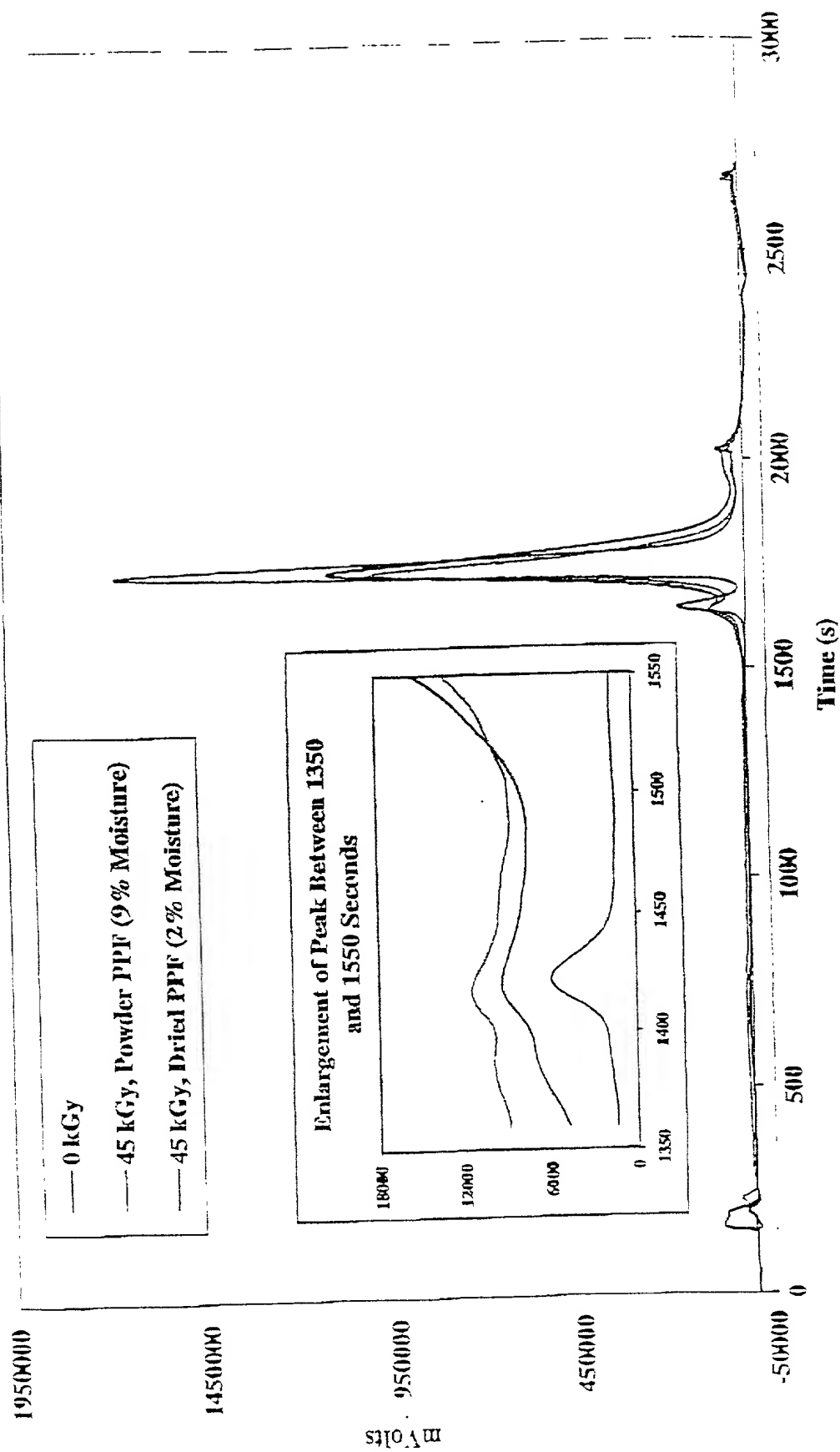
324

Gamma Irradiation of Dried and Powder PPF



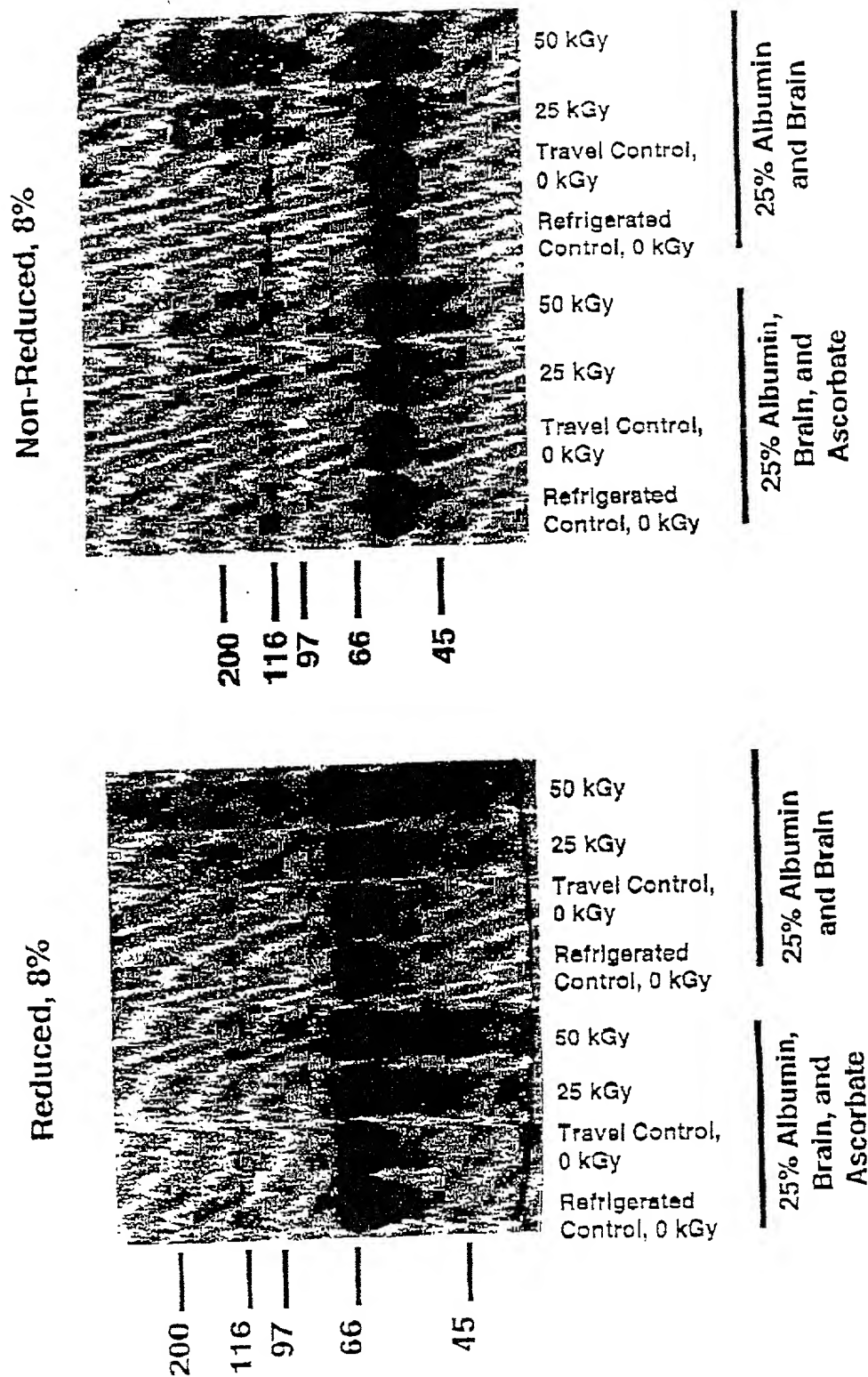
32B

Gamma Irradiation of Dried and Powder PPF



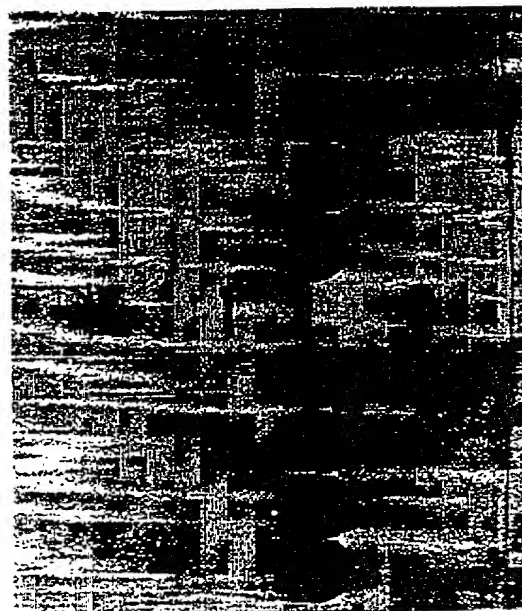
32C

Gamma Irradiation (to 25 and 50 kGy) of 25% Albumin in the Presence of Brain Alone or in Combination with 200 mM Ascorbate



Gamma Irradiation (to 25 and 50 kGy) of 25% Albumin in the Presence or Absence of 200 mM Ascorbate

Reduced, 8%



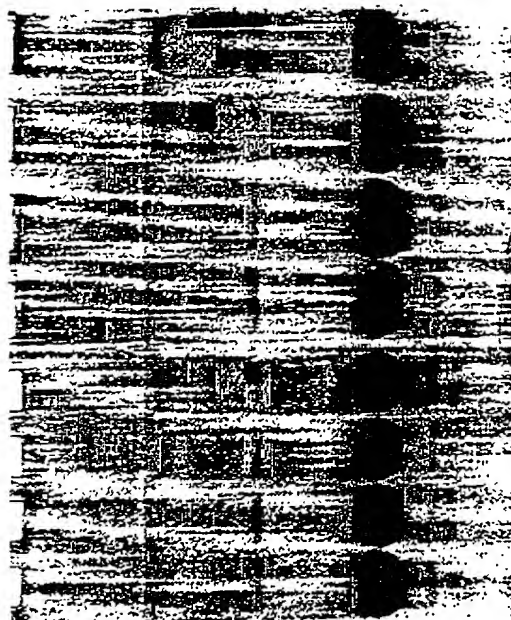
200
116
97
66
45

50 kGy
25 kGy
Travel Control, 0 kGy
Refrigerated Control, 0 kGy
50 kGy
25 kGy
Travel Control, 0 kGy
Refrigerated Control, 0 kGy

25% Albumin
And Ascorbate

25% Albumin

Non-Reduced, 8%



200
116
97
66
45

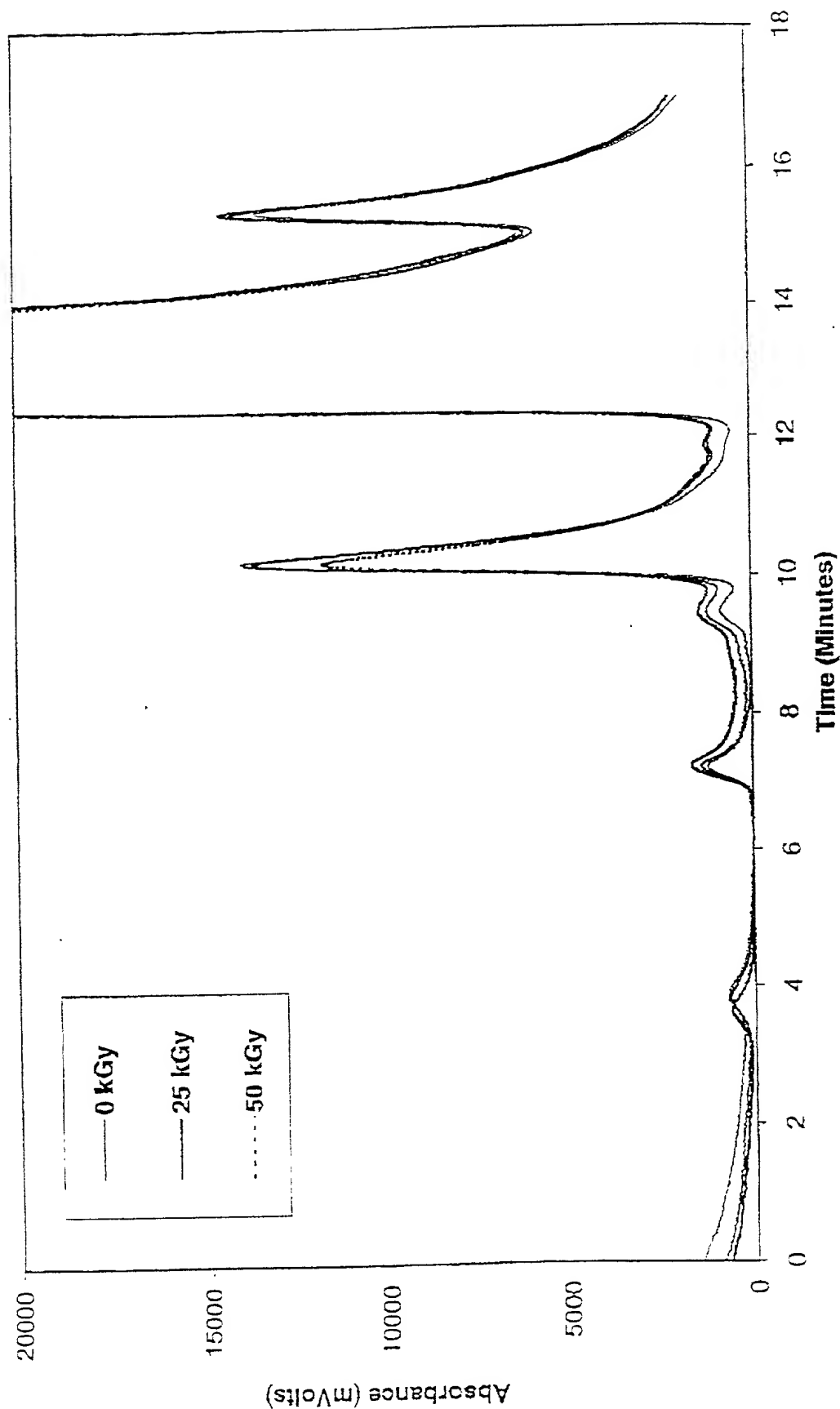
50 kGy
25 kGy
Travel Control, 0 kGy
Refrigerated Control, 0 kGy
50 kGy
25 kGy
Travel Control, 0 kGy
Refrigerated Control, 0 kGy

25% Albumin
And Ascorbate

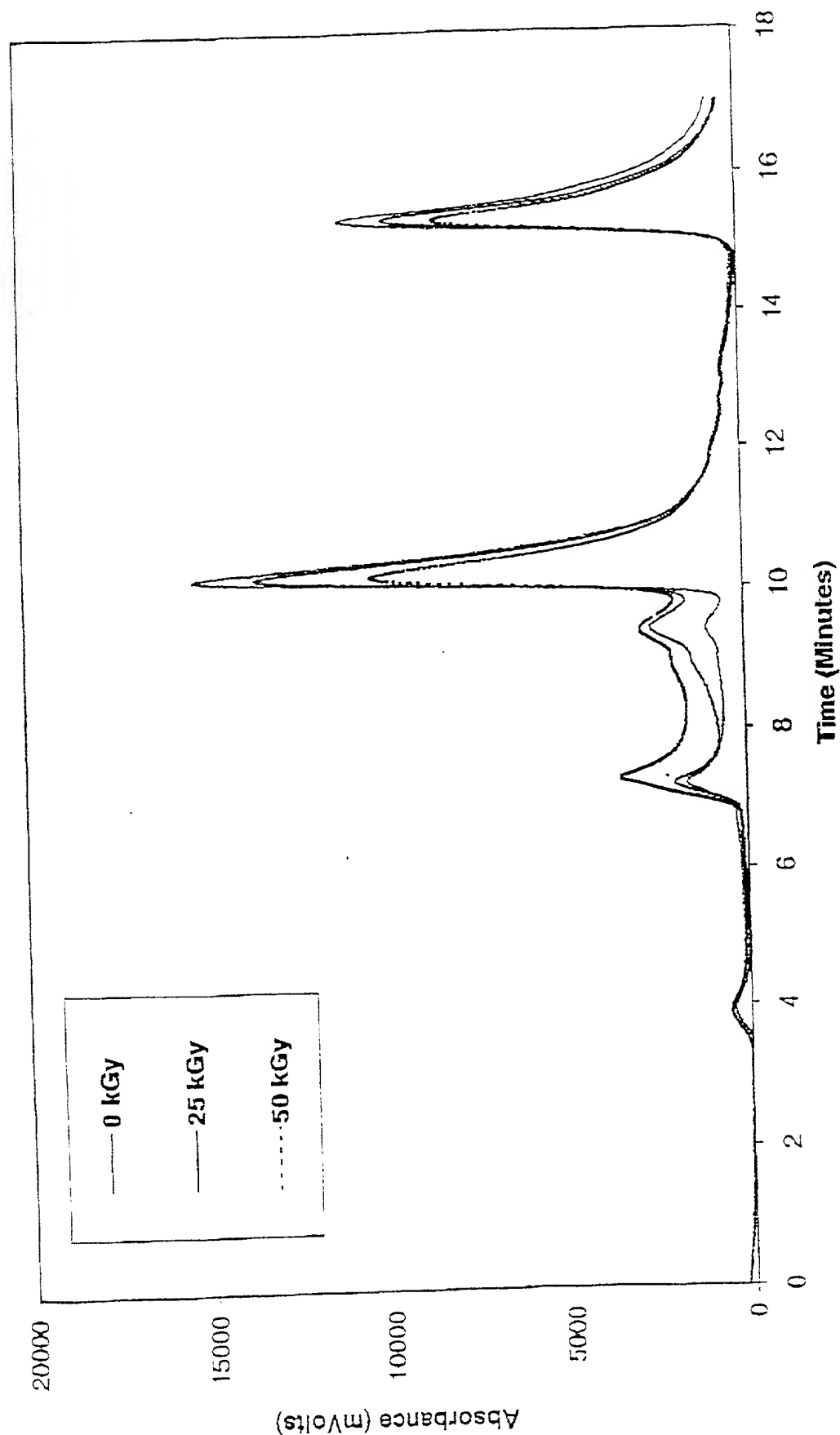
25% Albumin

33B

Gamma Irradiation of 25% Albumin in the Presence of Brain and 200 mM Ascorbate

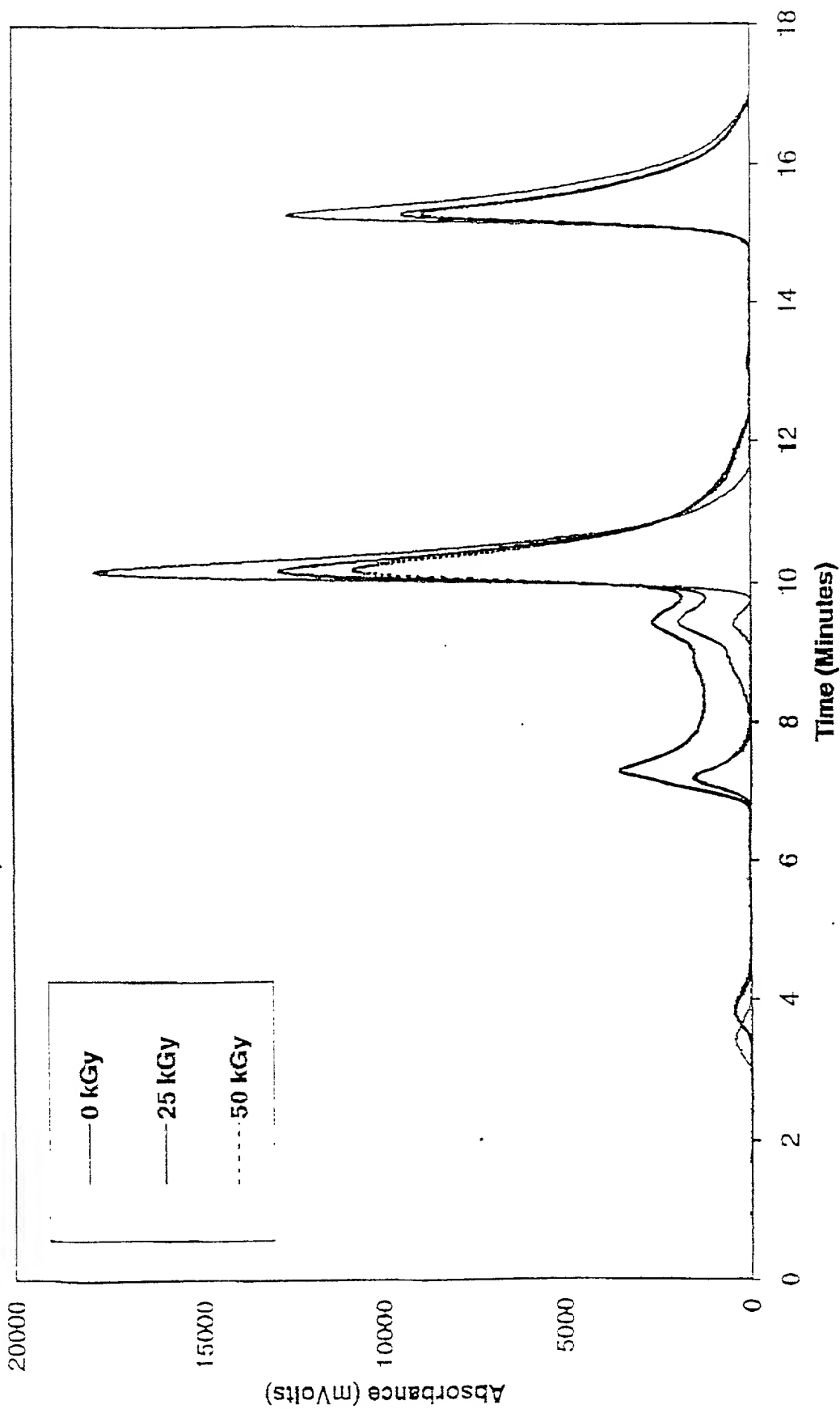


Gamma Irradiation of 25% Albumin in the Presence of Brain



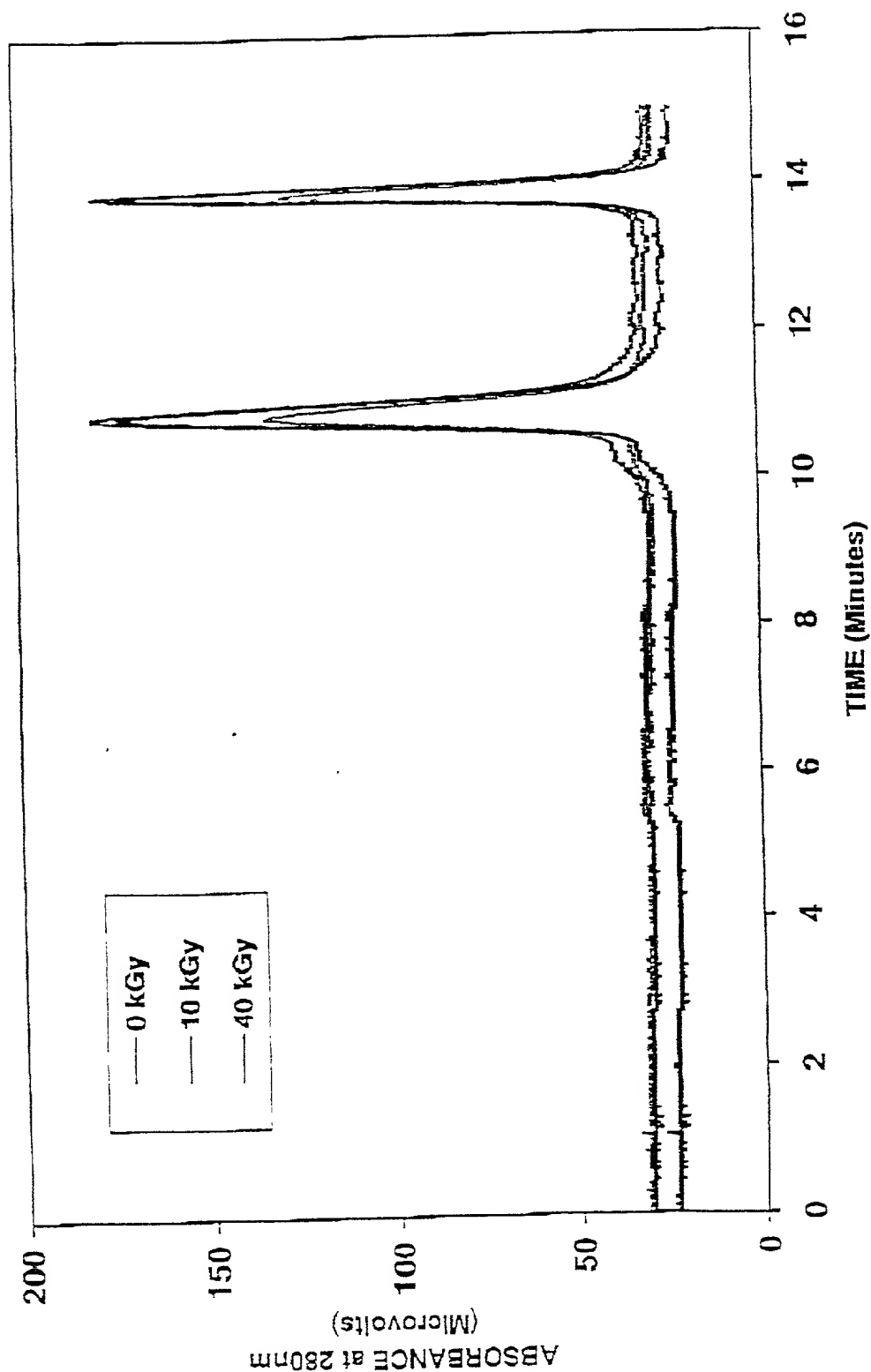
33D

Gamma Irradiation of 25% Albumin



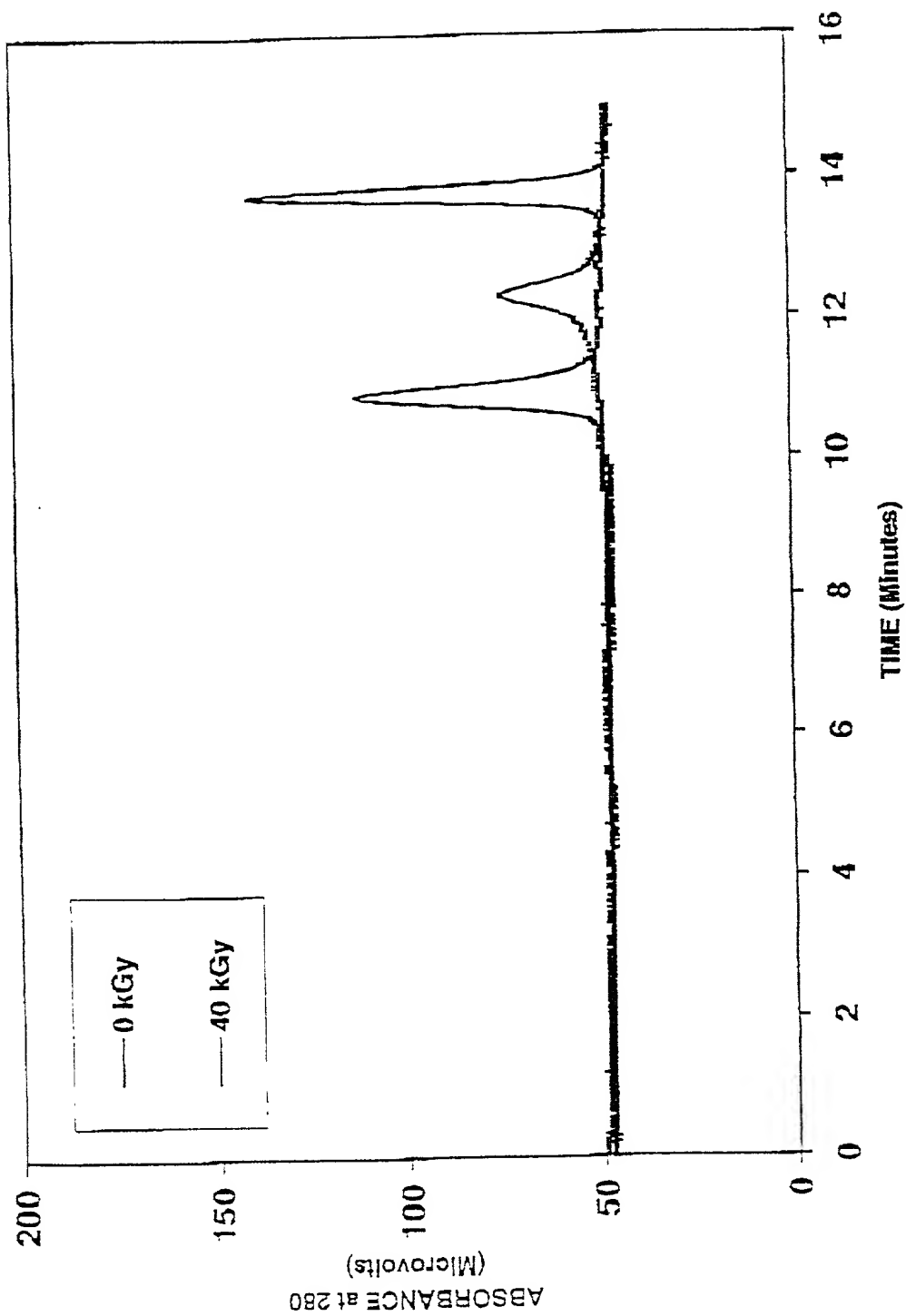
33F

Gamma Irradiation of Lyophilized Albumin



34A

Gamma Irradiation of Liquid Albumin



34B

25% Albumin - Non-Reduced

1 2 3 4 5 6 7 8 9 10 11 12

Std	Lane	Sample
Kd	1	Empty
	2	Broad Range Std. (BioRad)
200	3	Empty
116	4	0 Kgy (Control) Box 3C (- Ar)
97	5	18.0 Kgy (≈ 0.91 Kgy/hr) Box 1 (- Ar)
66	6	23.0 Kgy (≈ 0.92 Kgy/hr) Box 2 (- Ar)
45	7	30.4 Kgy (≈ 1.01 Kgy/hr) Box 3 (- Ar)
	8	0 Kgy (Control) Box 3C (- Ar)
31	9	18.0 Kgy (≈ 0.91 Kgy/hr) Box 1 (- Ar)
21.5	10	23.0 Kgy (≈ 0.92 Kgy/hr) Box 2 (- Ar)

14.4 11 30.4 Kgy (≈ 1.01 Kgy/hr) Box 3 (- Ar)
12 Empty

35A

25% Albumin - Reduced

1 2 3 4 5 6 7 8 9 10 11 12

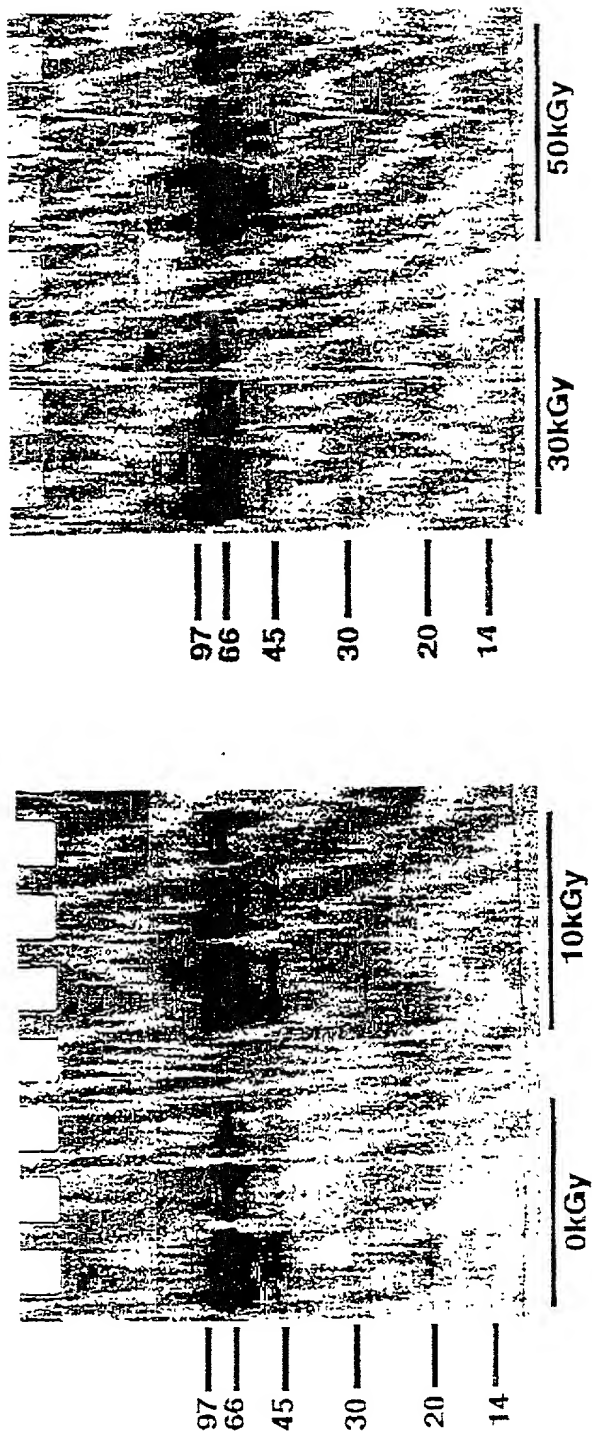
Std	Lane	Sample
Kd	1	Empty
	2	Broad Range Std. (BioRad)
200	3	Empty
116	4	0 Kgy (Control) Box 3C (- Ar)
97	5	18.0 Kgy (≈ 0.91 Kgy/hr) Box 1 (- Ar)
66	6	23.0 Kgy (≈ 0.92 Kgy/hr) Box 2 (- Ar)
45	7	30.4 Kgy (≈ 1.01 Kgy/hr) Box 3 (- Ar)
	8	0 Kgy (Control) Box 3C (- Ar)
31	9	18.0 Kgy (≈ 0.91 Kgy/hr) Box 1 (- Ar)
21.5	10	23.0 Kgy (≈ 0.92 Kgy/hr) Box 2 (- Ar)

14.4 11 30.4 Kgy (≈ 1.01 Kgy/hr) Box 3 (- Ar)
12 Empty

35B

TOP SECRET
Gamma Irradiation of Powder PPF at -20°C

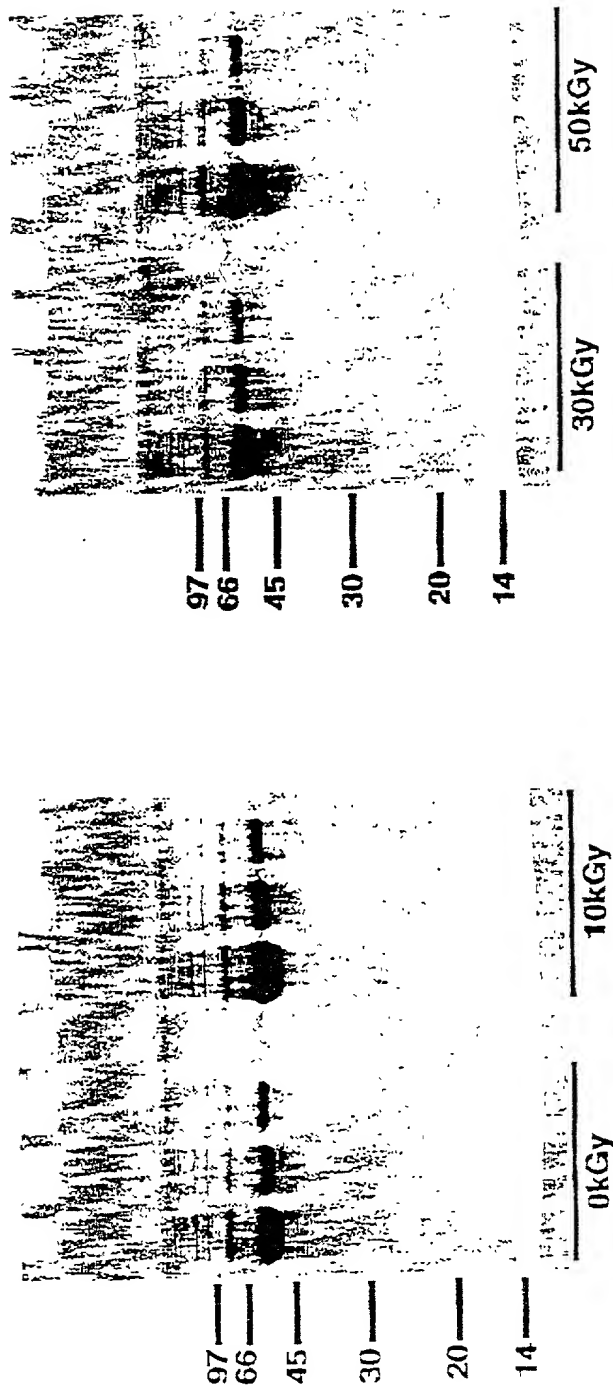
Reduced



36A

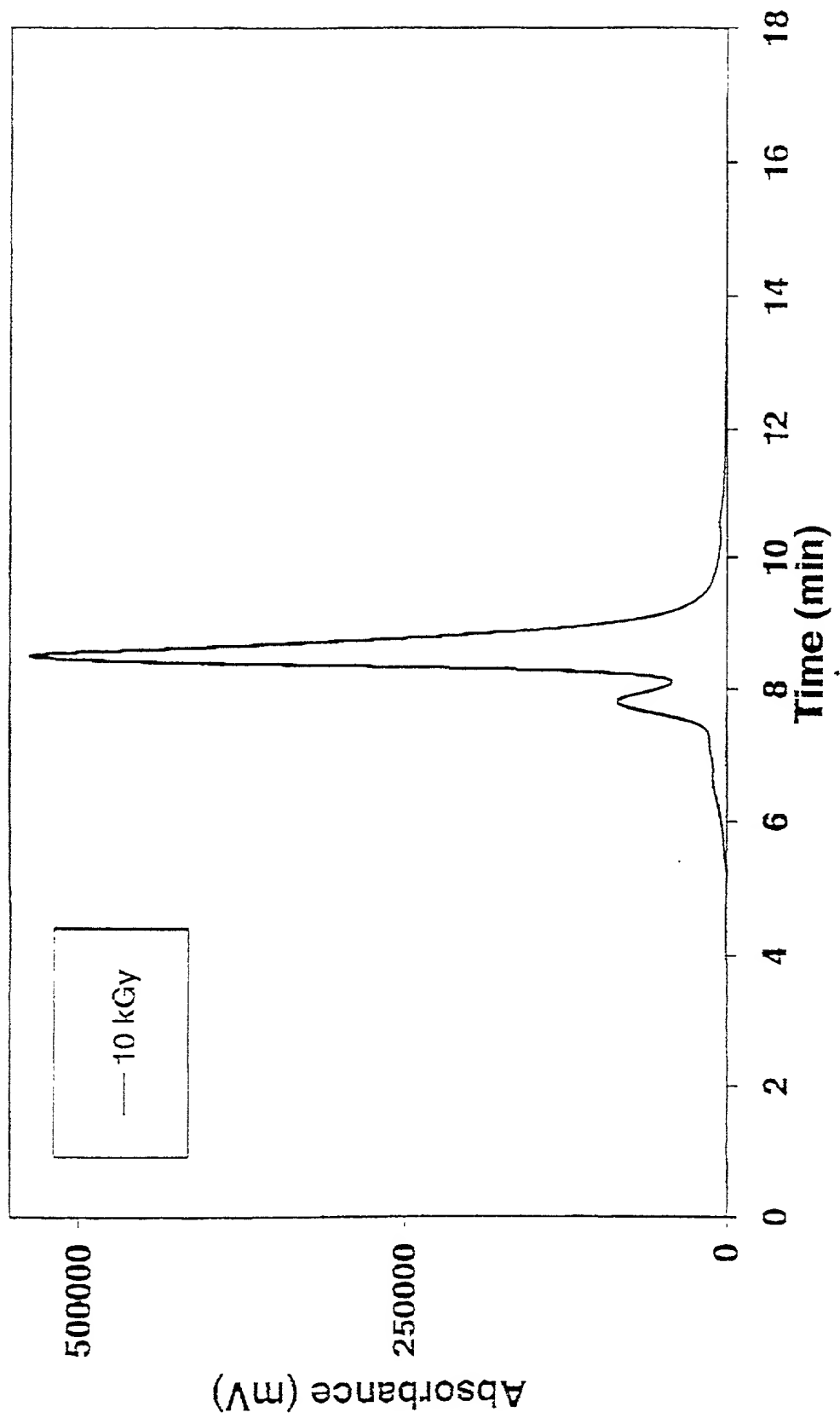
Gamma Irradiation of Powder PPF at -20°C

Nonreduced



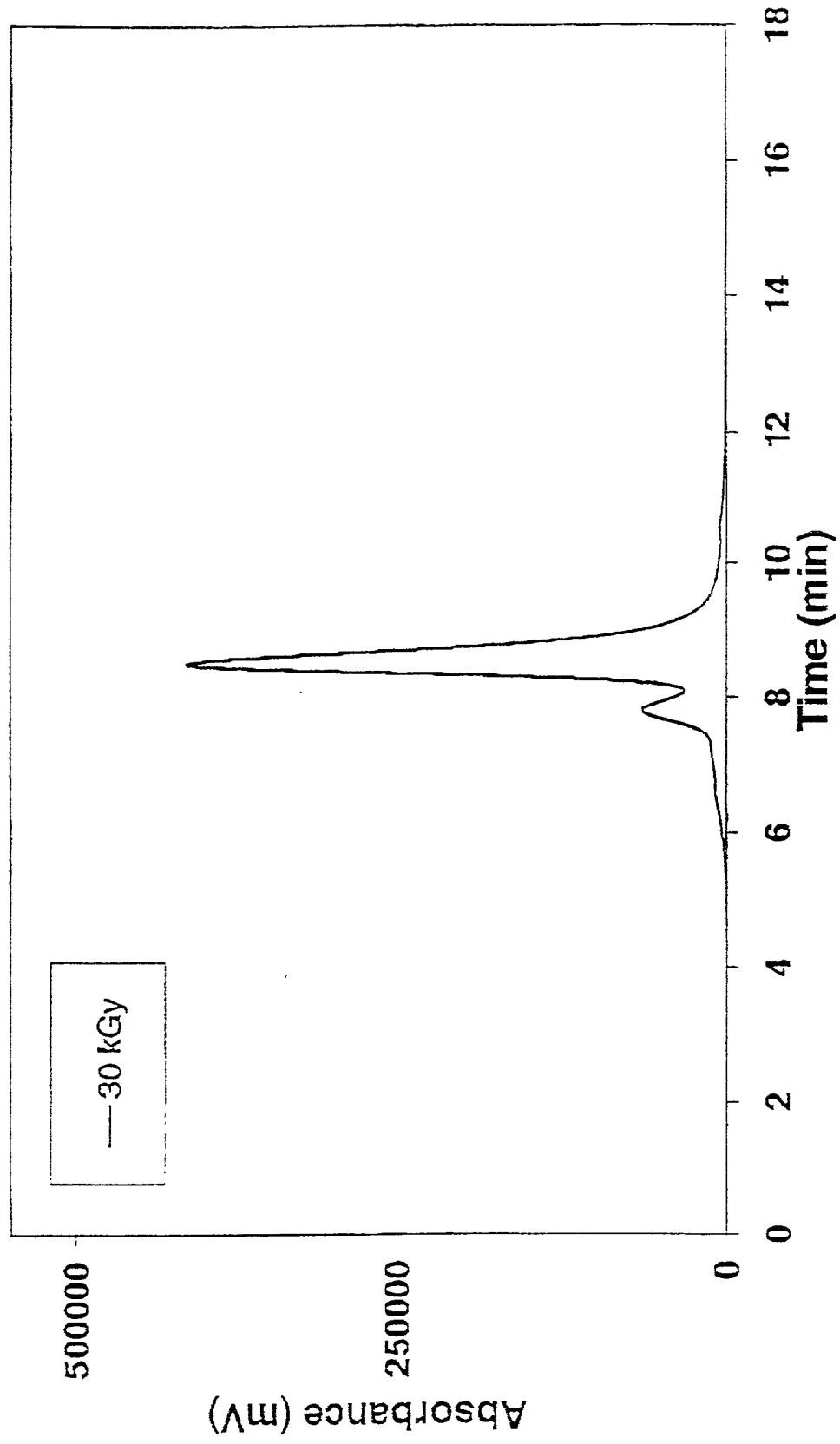
36B

Gamma Irradiation of Powder PPF



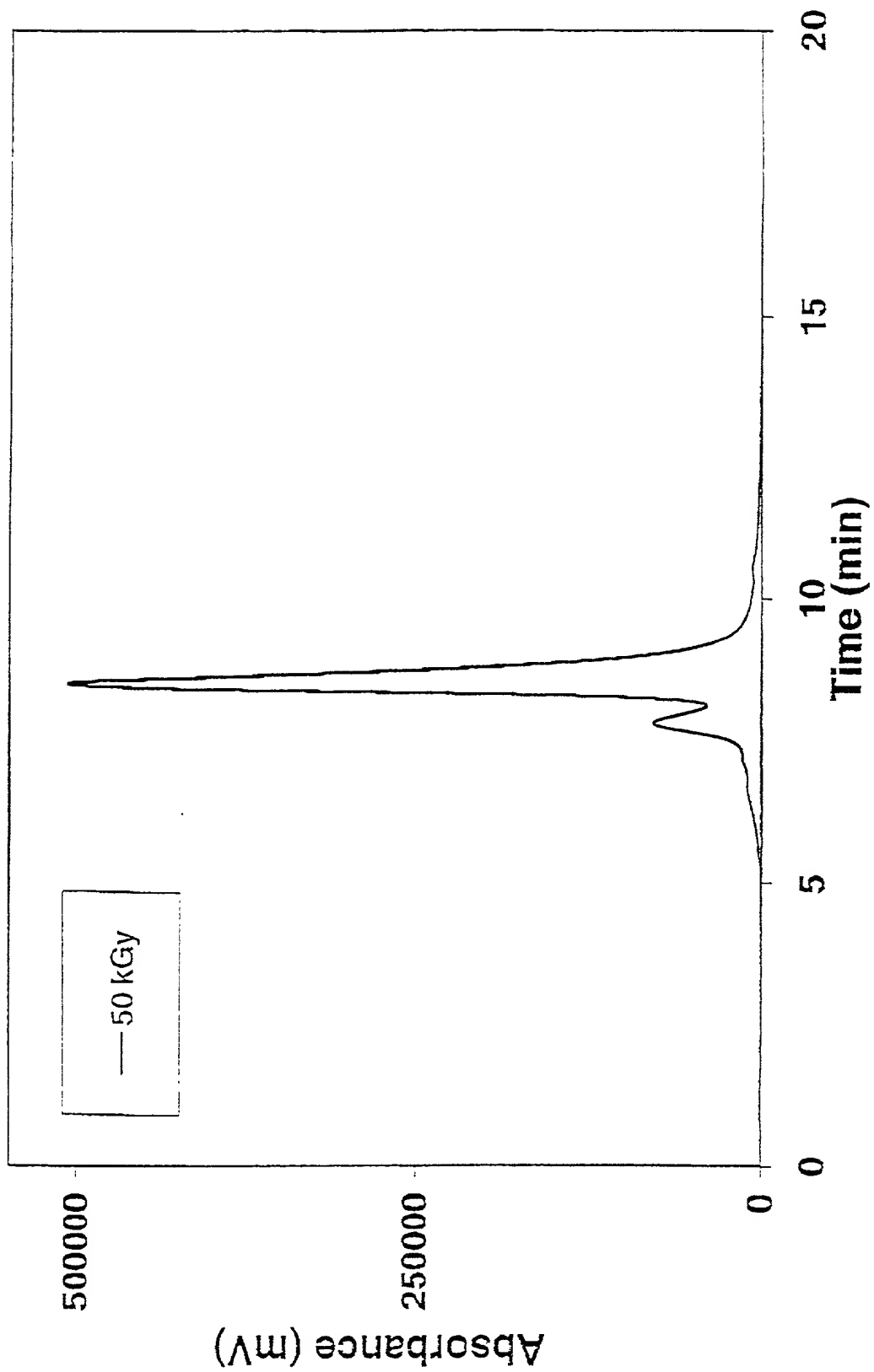
36D

Gamma Irradiation of Powder PPF



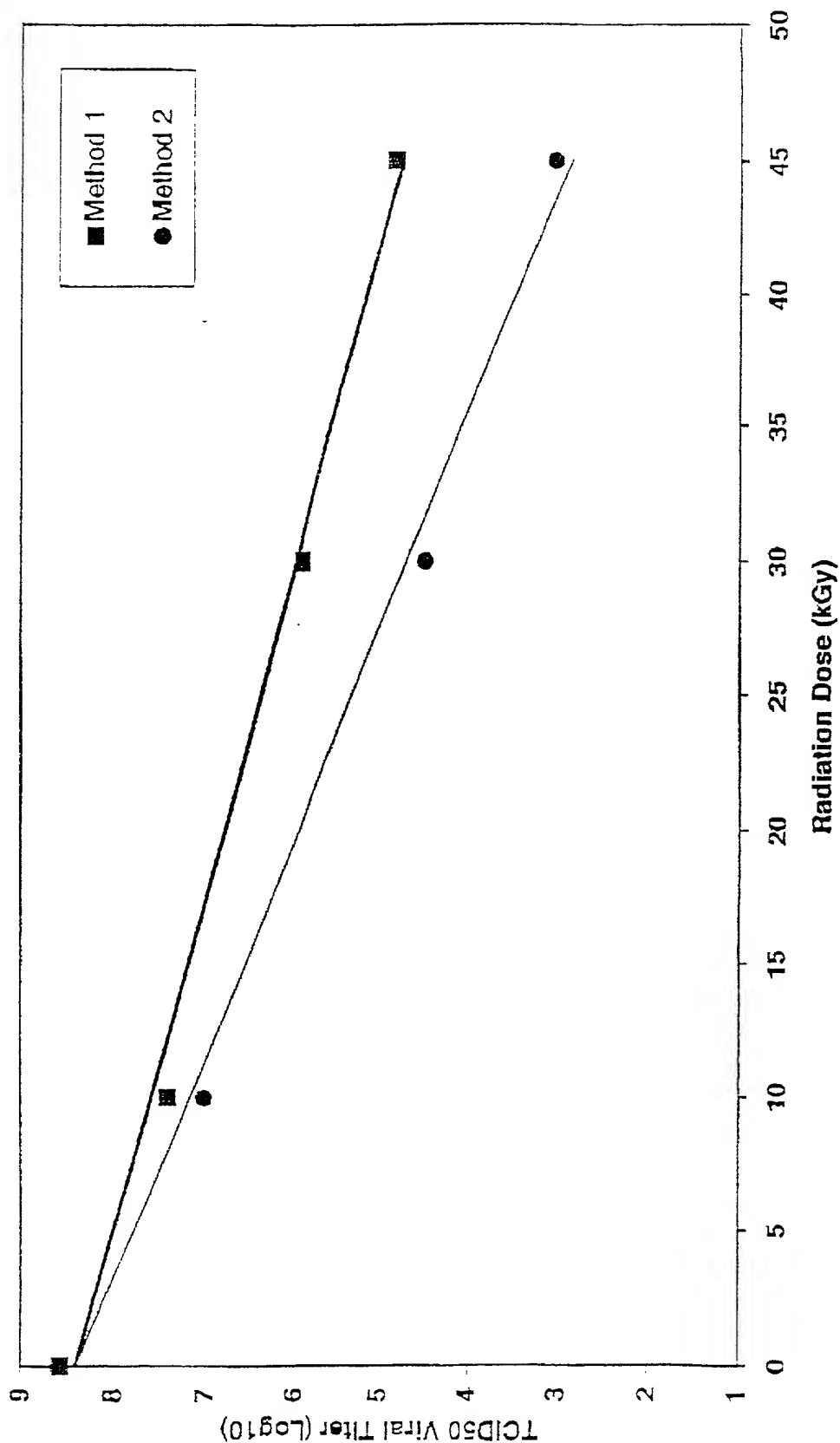
36E

Gamma Irradiation of Powder PPF



36F

Gamma Irradiation of PPV in PPF by Irradiation at -80oC

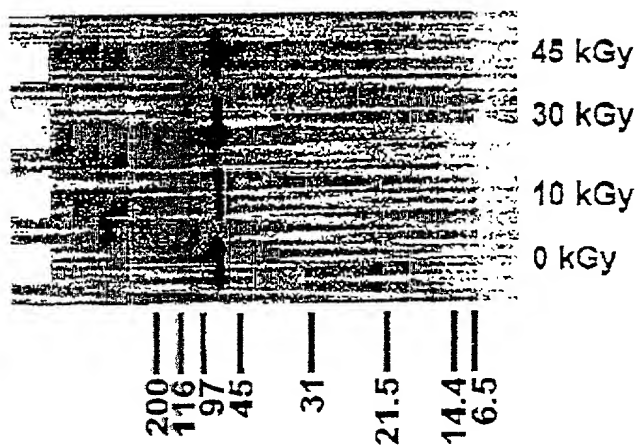
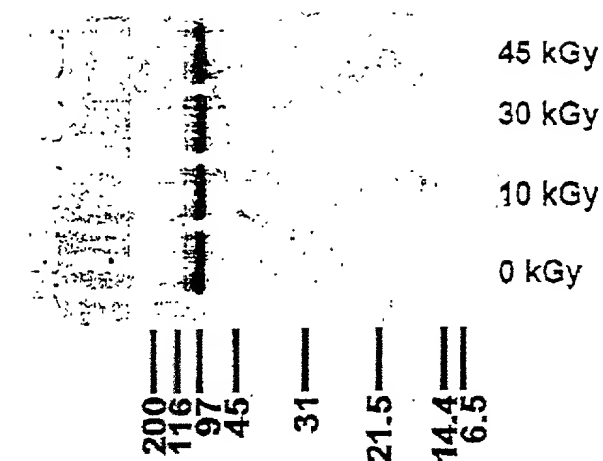


37A

Gamma Irradiation of PPF By Method 2

Reduced 12.5%

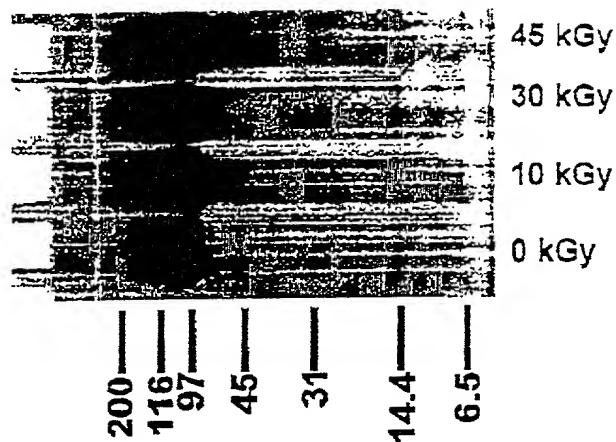
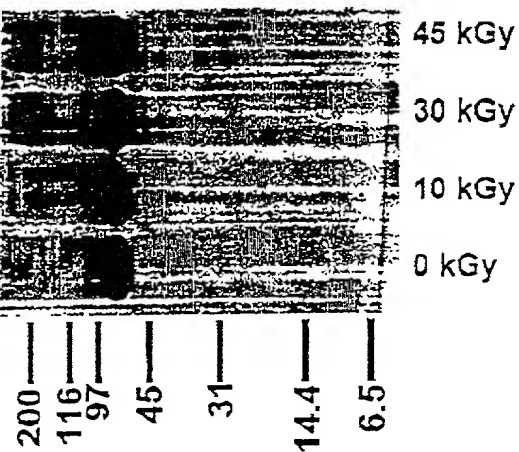
Nonreduced, 12.5%



37B

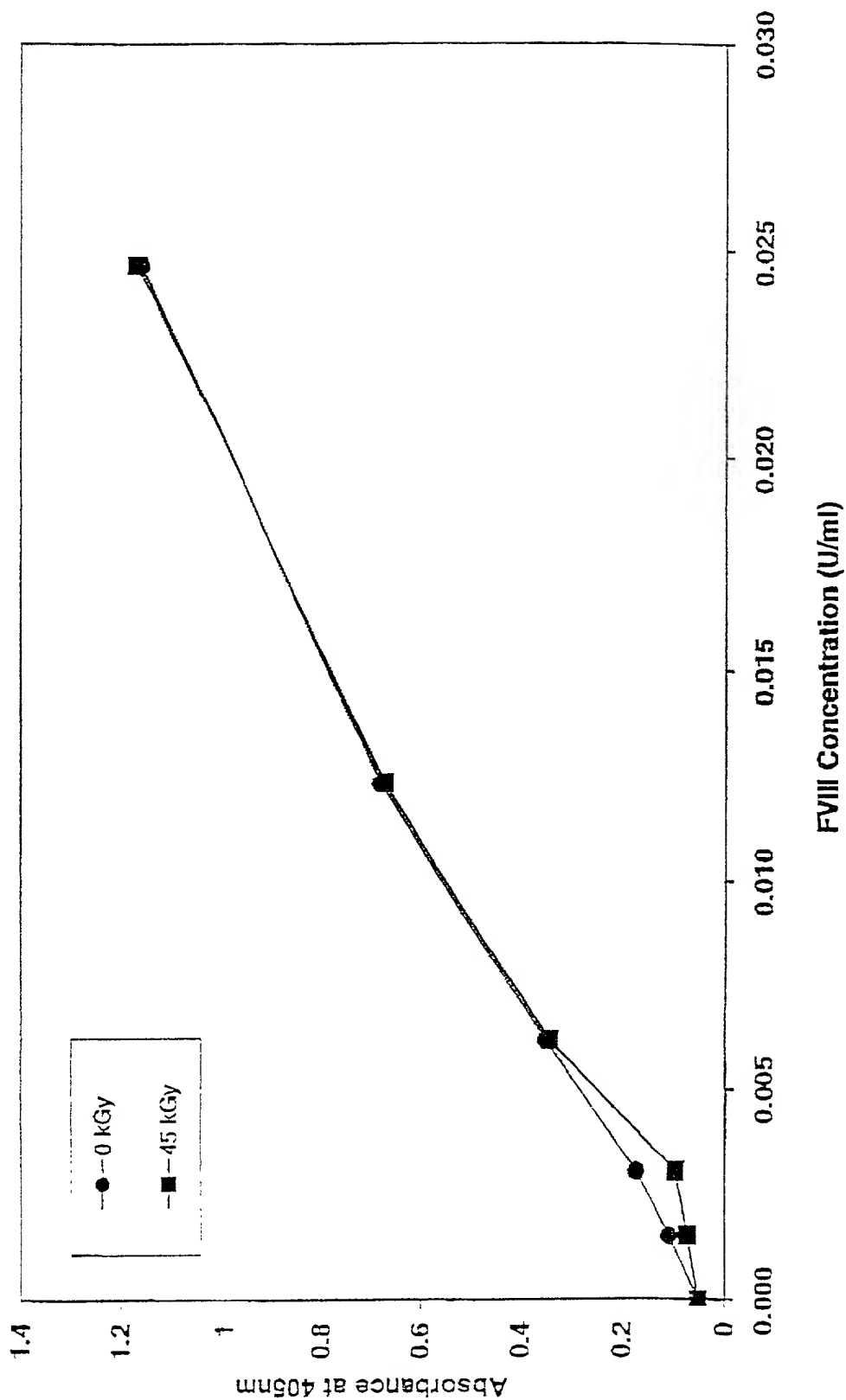
083101.alb.04/073001.jla.016 Gamma Irradiation of PPF By Method 1

Nonreduced, 12.5% Reduced, 12.5%

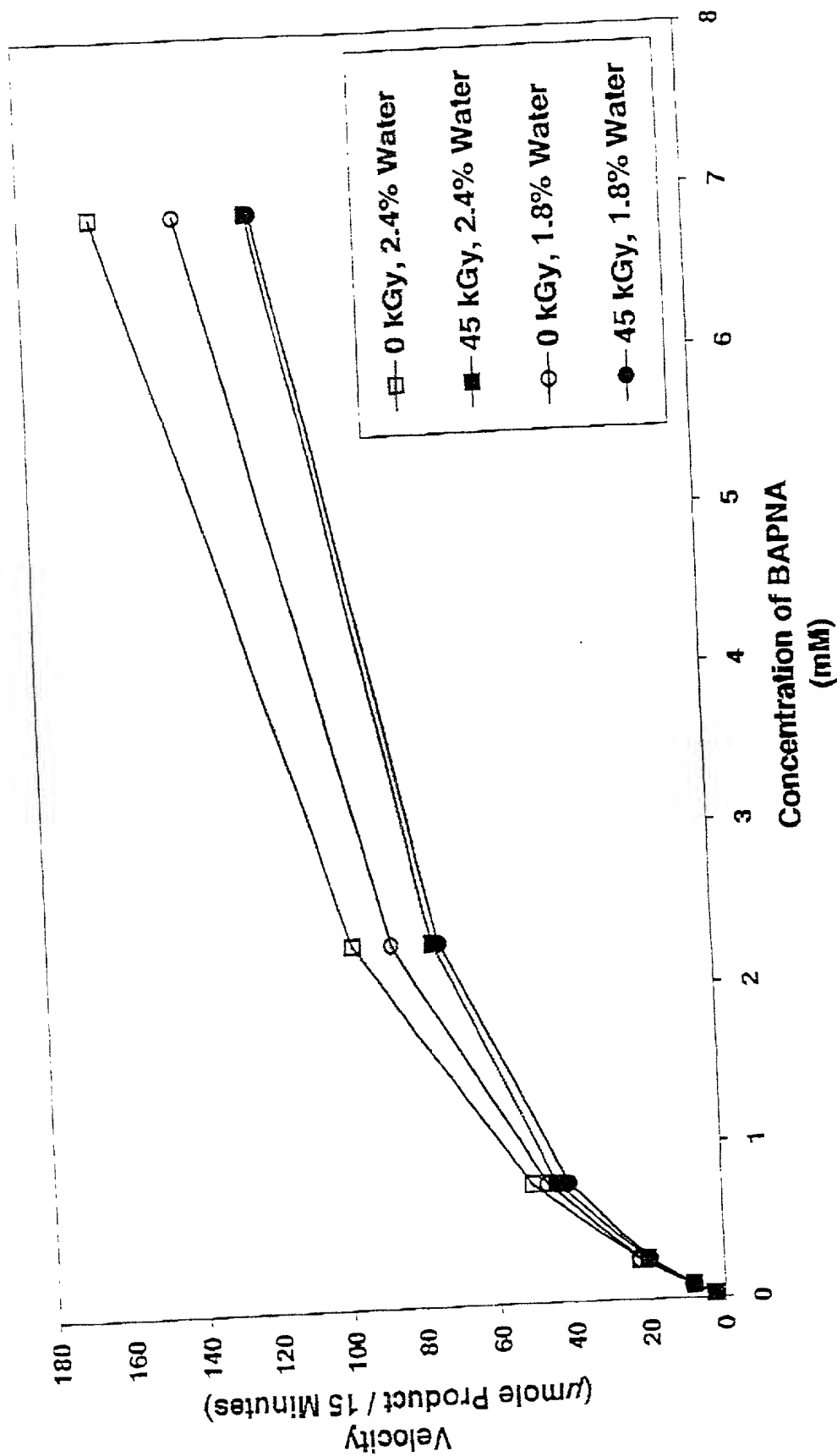


37C

Gamma Irradiation of FVIII

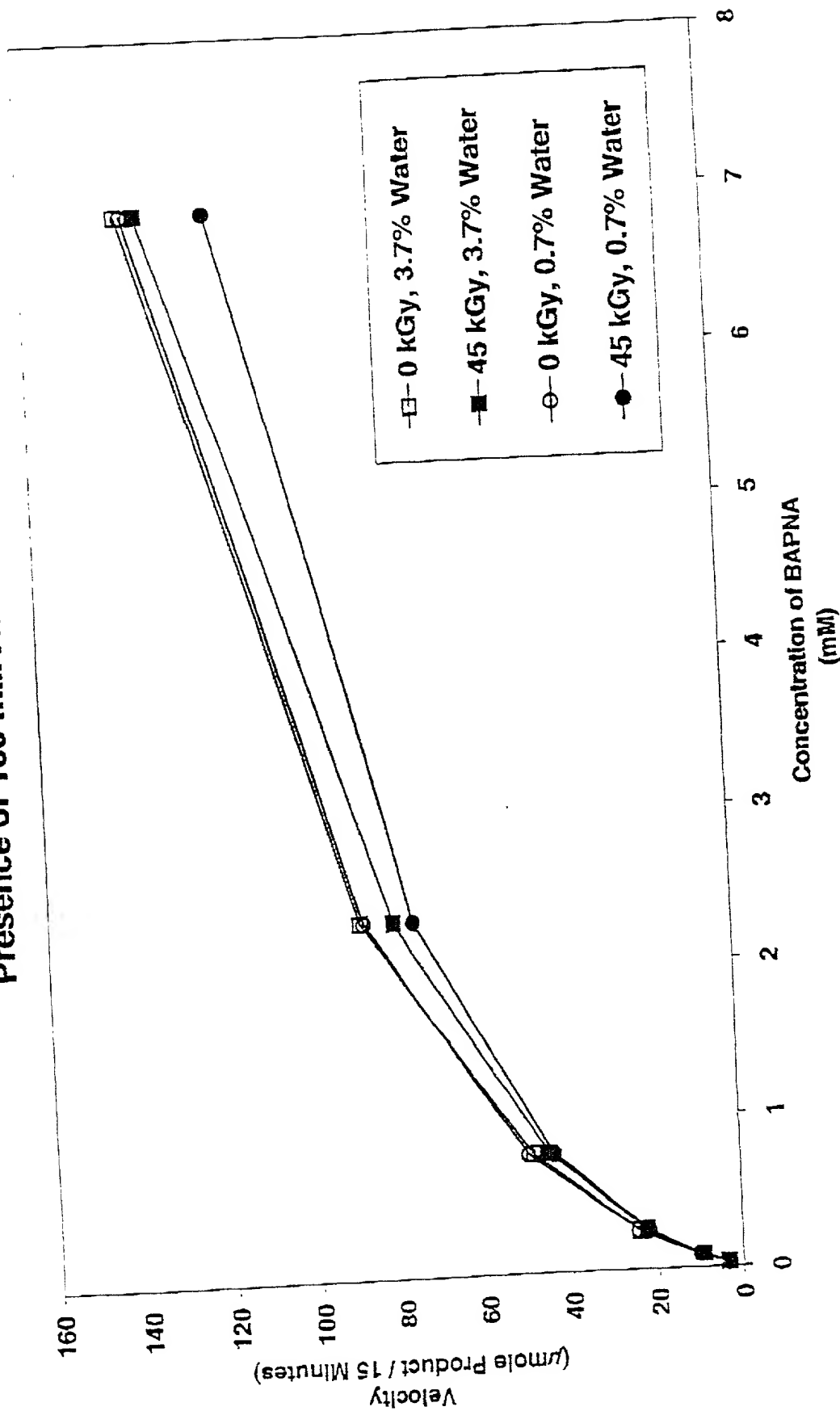


Gamma Irradiation of Lyophilized Trypsin In the Absence of Ascorbate



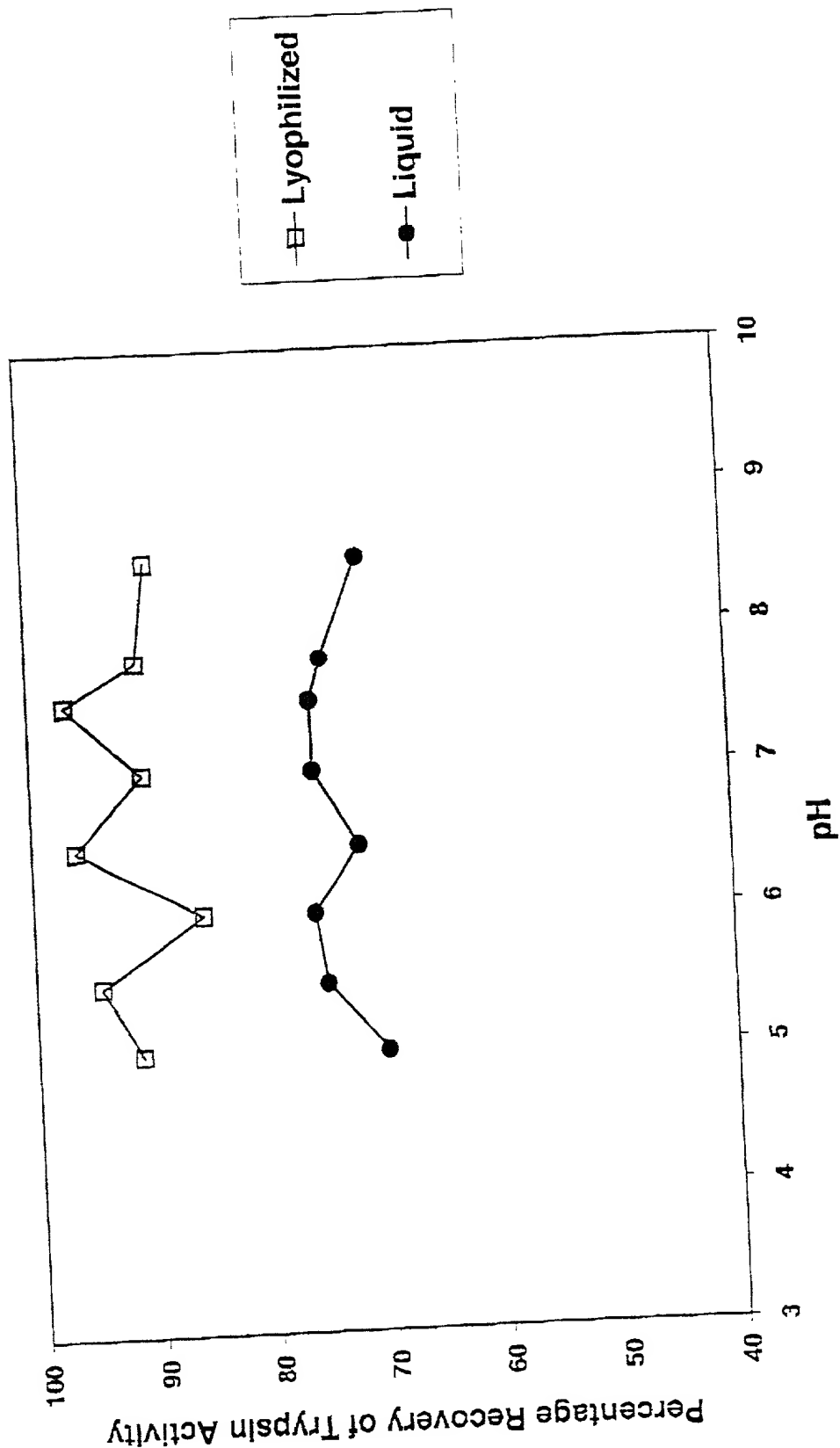
39A

Gamma Irradiation of Lyophilized Trypsin In the Presence of 100 mM Ascorbate

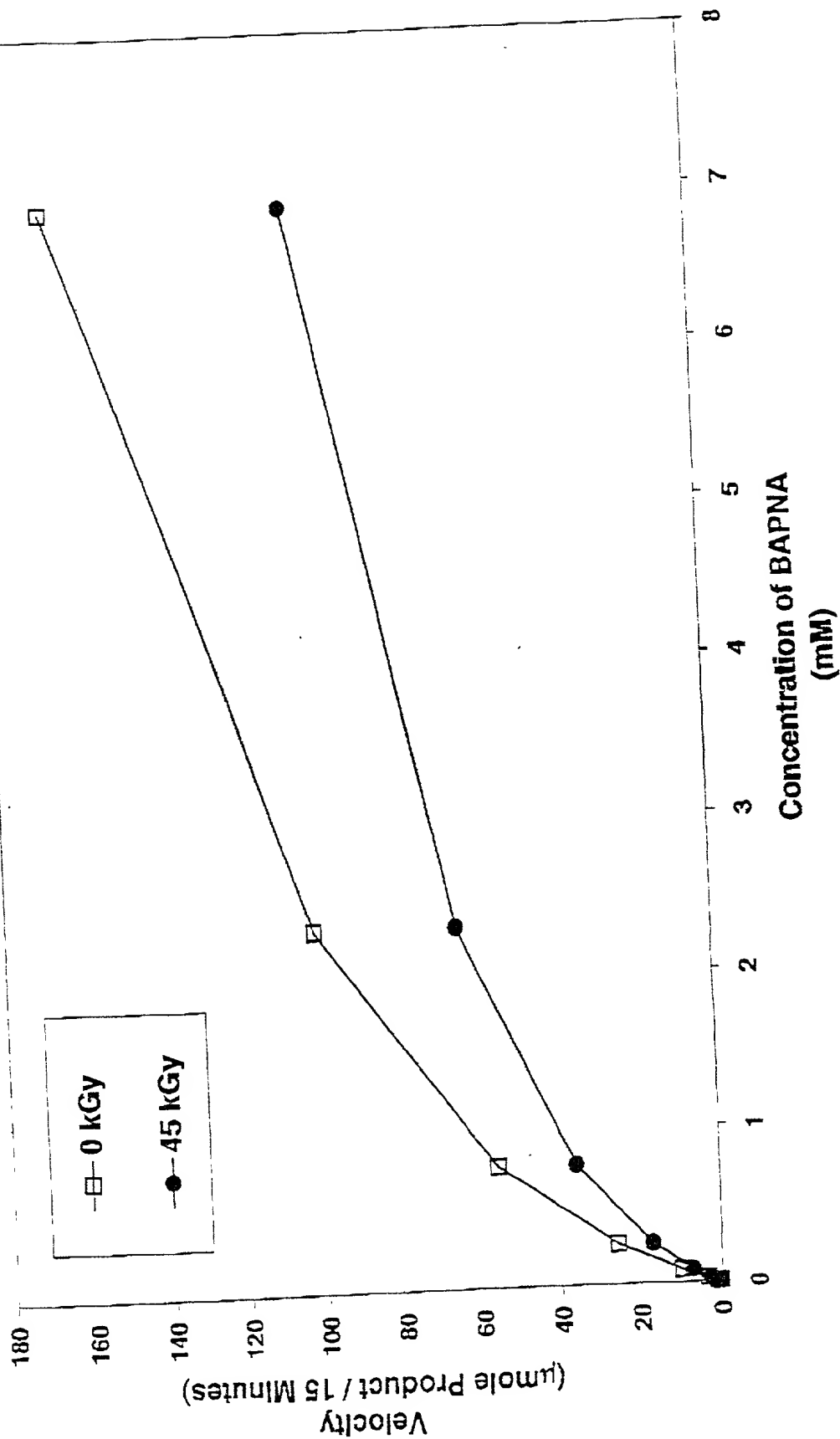


39B

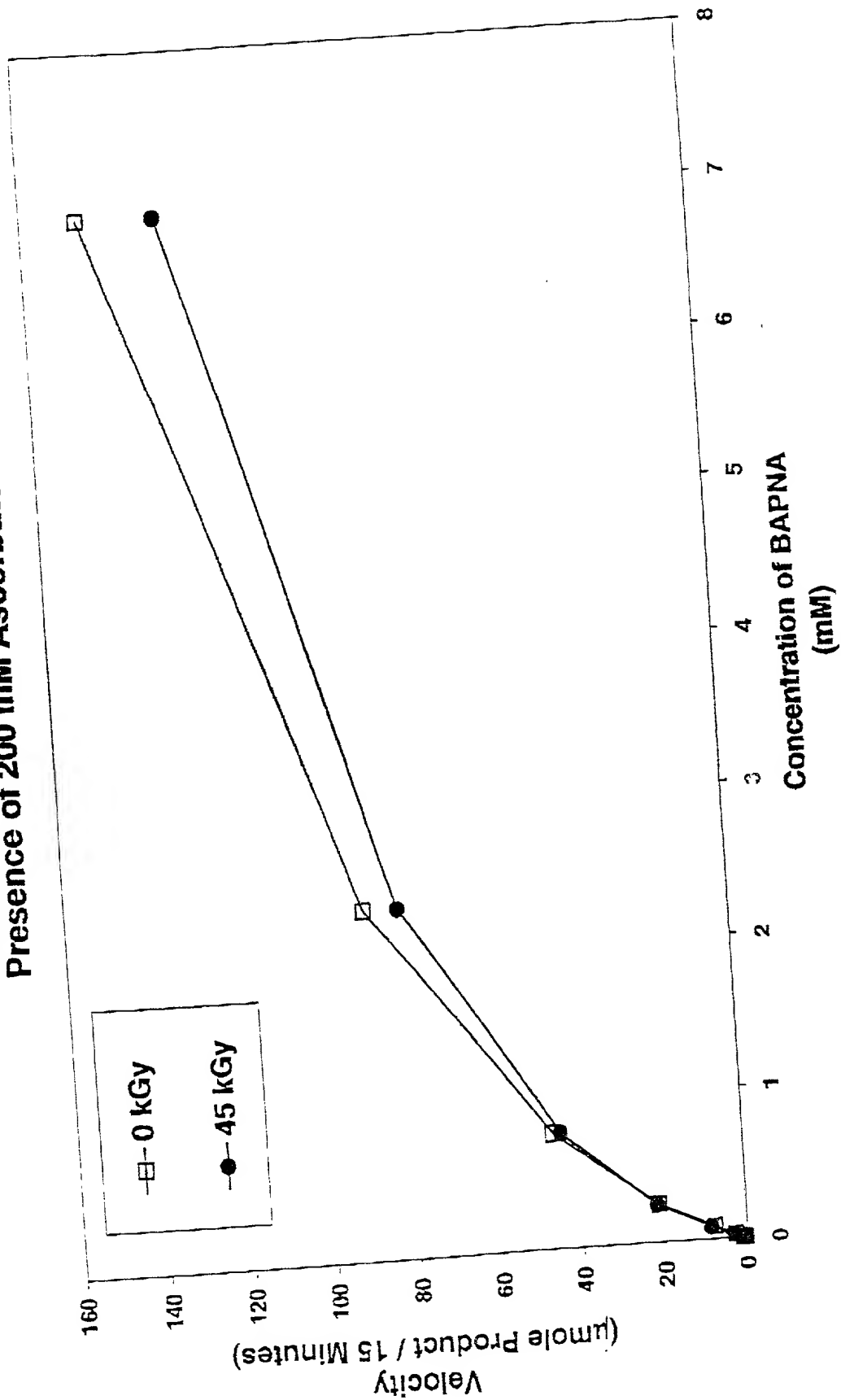
Gamma Irradiation of Two Forms of Trypsin In the Presence of 200 mM Ascorbate



Gamma Irradiation of Lyophilized Trypsin in the Absence of Ascorbate

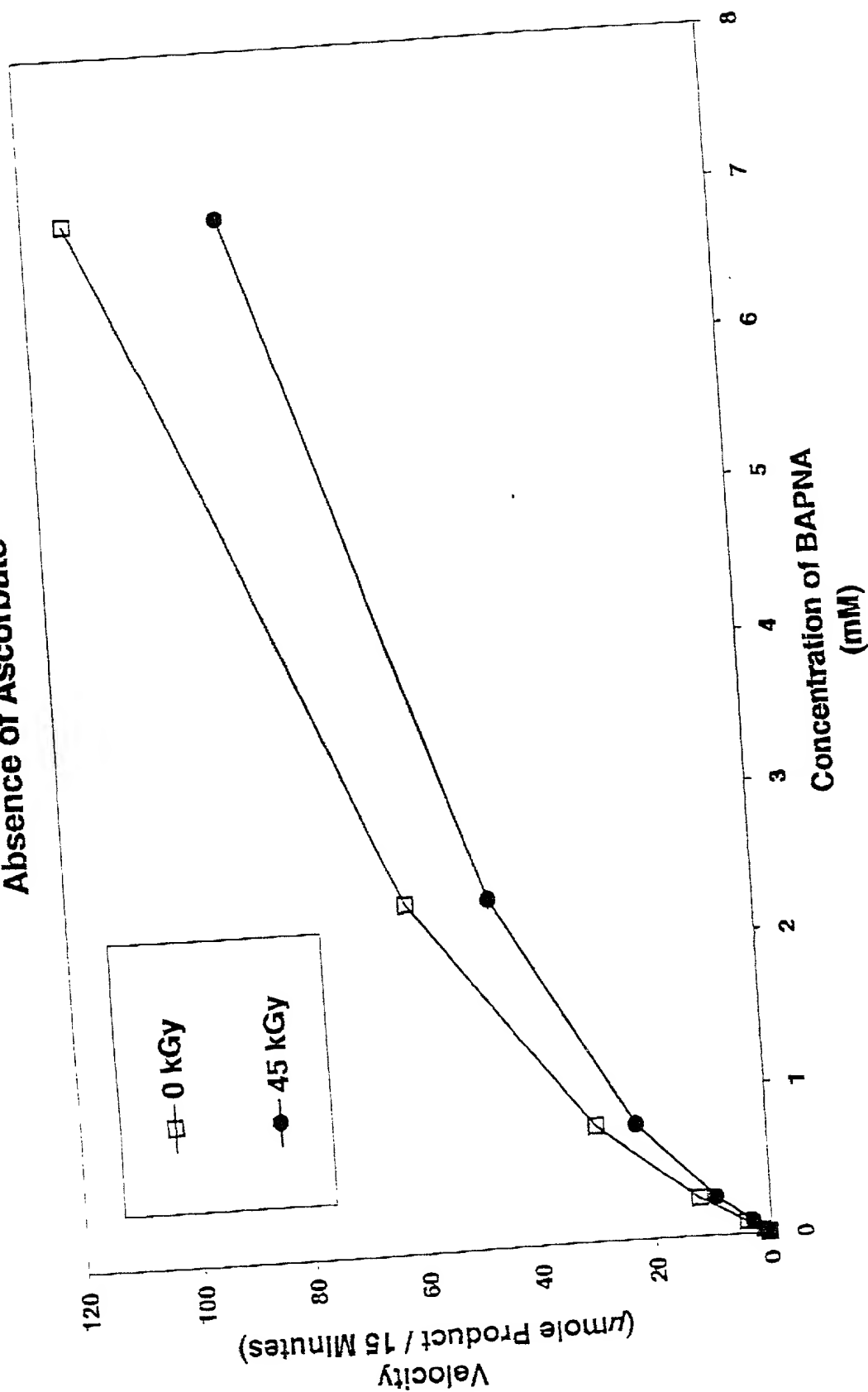


Gamma Irradiation of Lyophilized Trypsin In the Presence of 200 mM Ascorbate



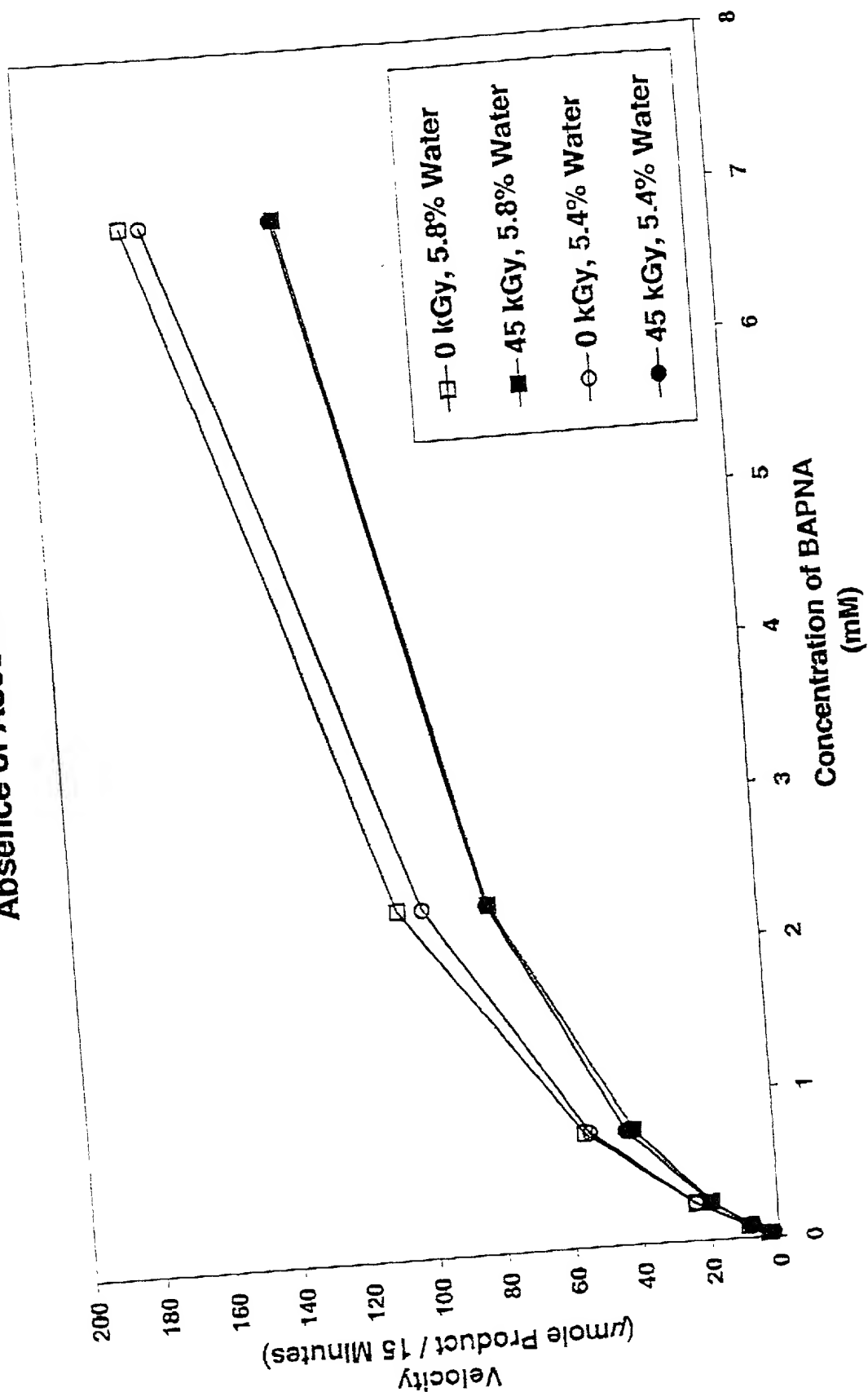
41B

Gamma Irradiation of Lyophilized Trypsin in the Absence of Ascorbate



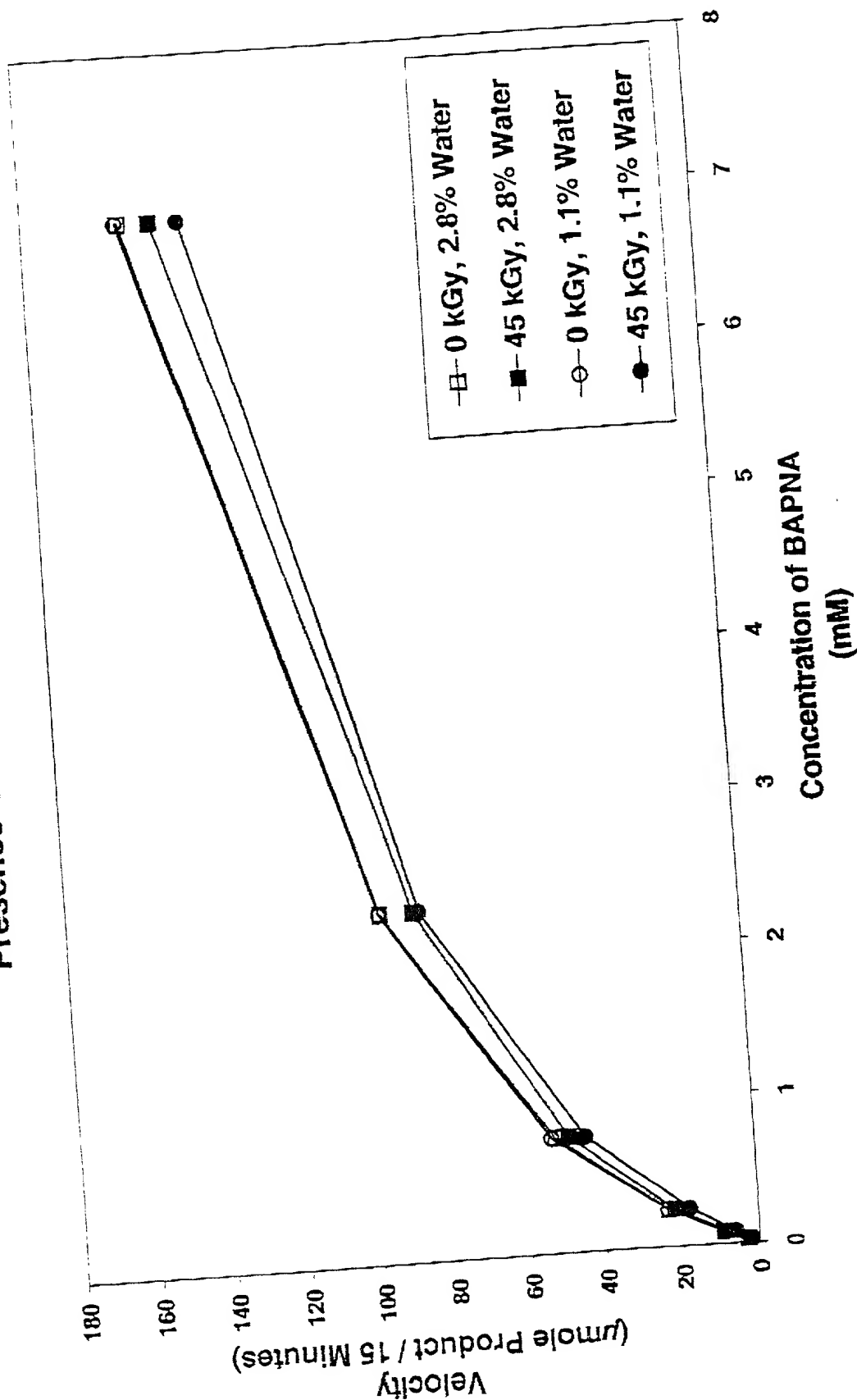
42A

Gamma Irradiation of Lyophilized Trypsin In the Absence of Ascorbate



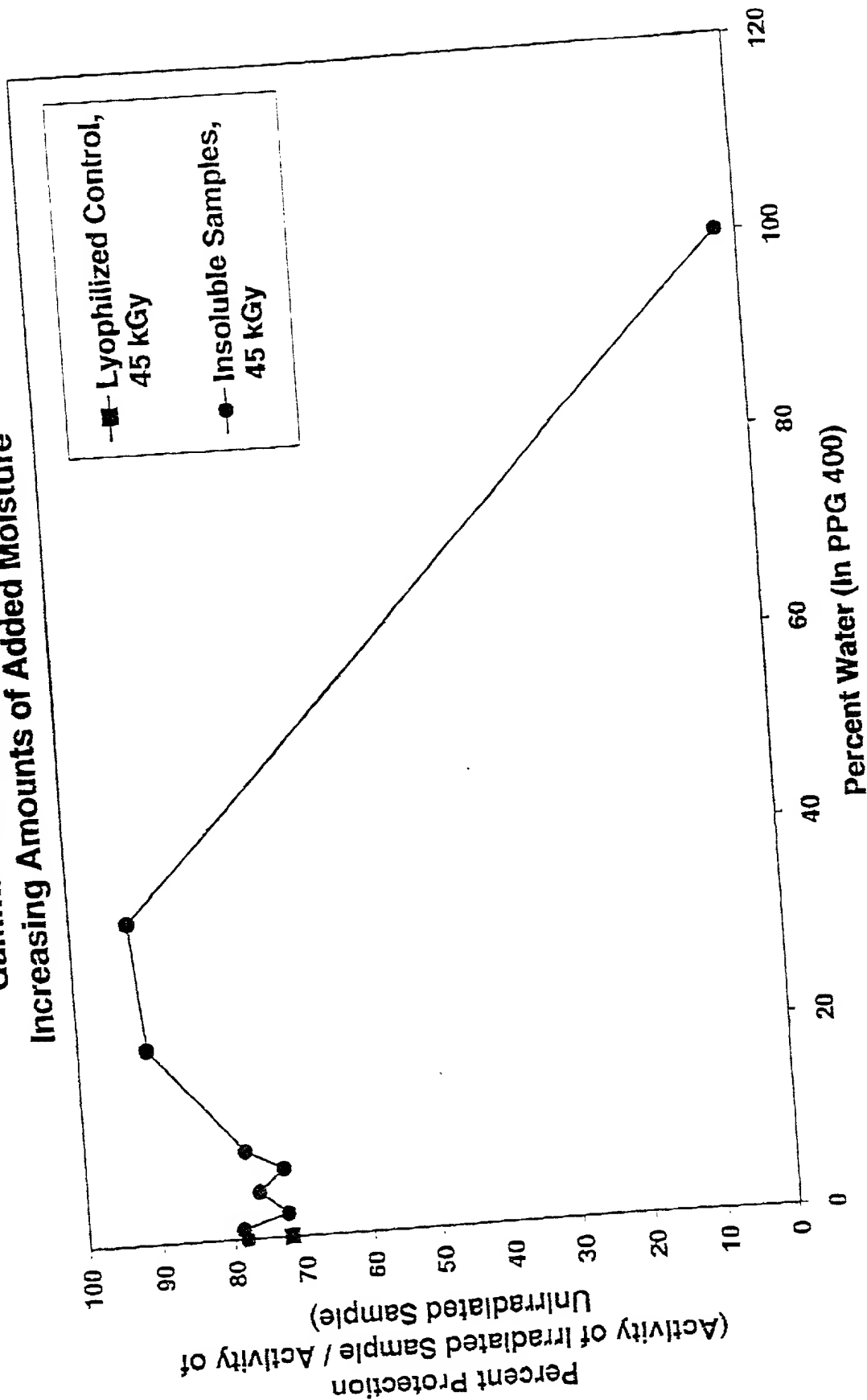
43A

Gamma Irradiation of Lyophilized Trypsin In the Presence of 100 mM Ascorbate

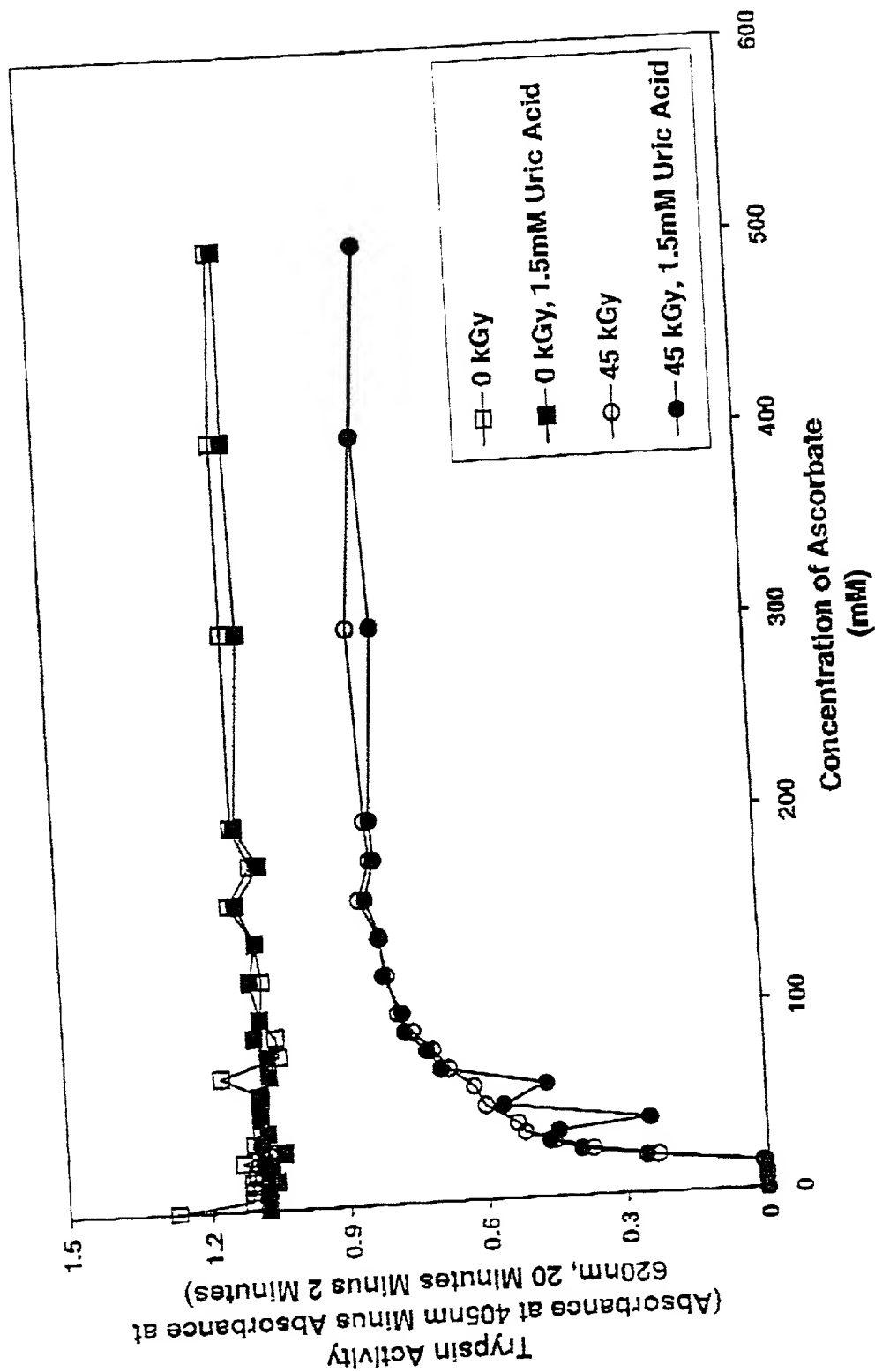


43B

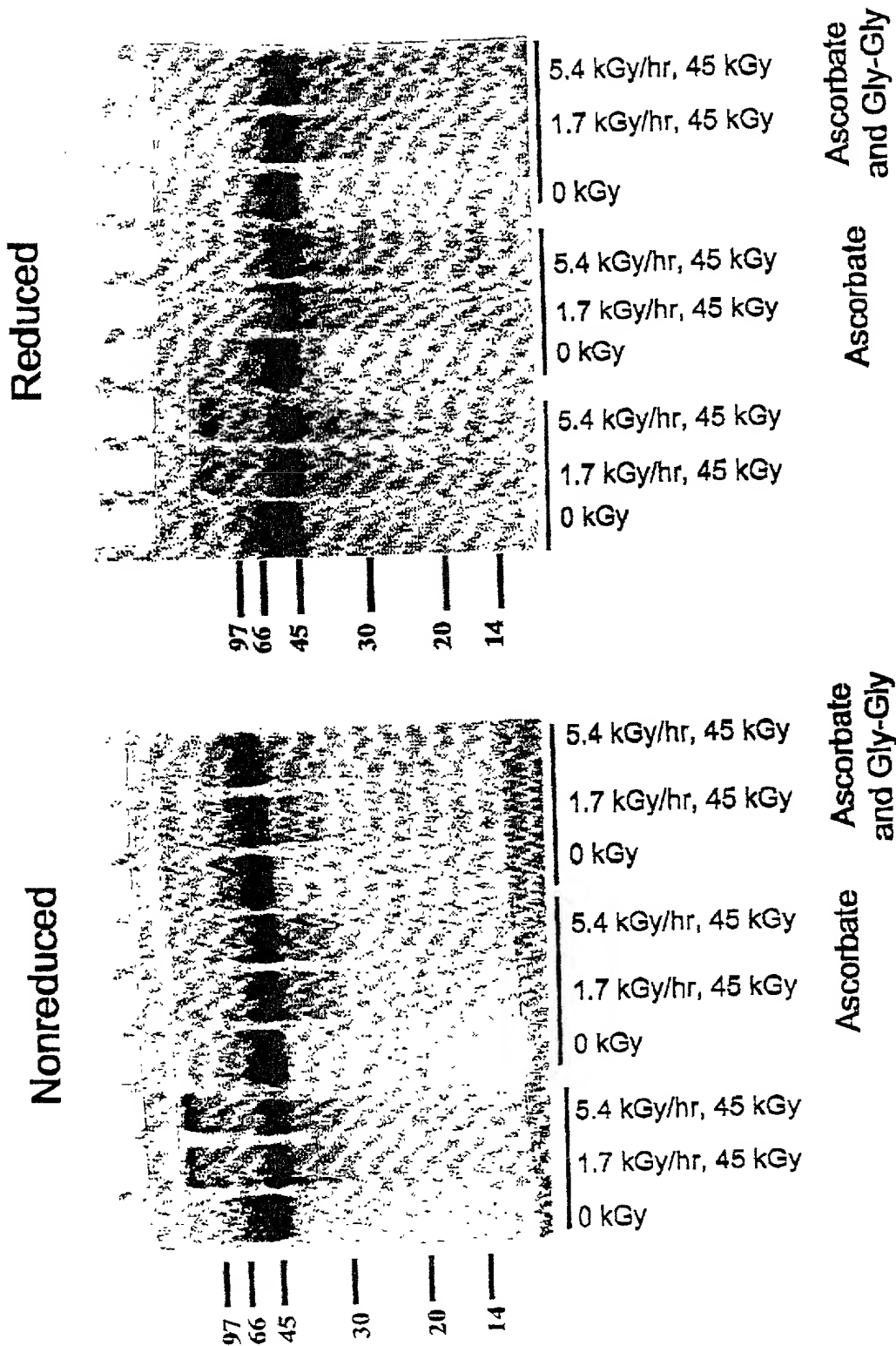
Gamma Irradiation of Trypsin in the Presence of Increasing Amounts of Added Moisture



Gamma Irradiation of Liquid Trypsin in the Presence of Increasing Concentrations of Ascorbate



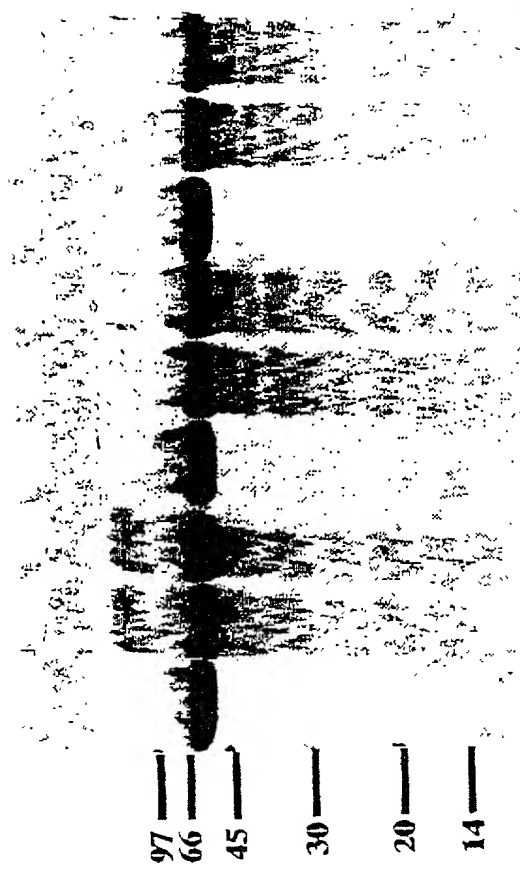
SDS-PAGE for a Glycosidase



46A

SDS-PAGE for a Sulfatase

Reduced



5.4 kGy/hr, 45 kGy

1.7 kGy/hr, 445 kGy

0 kGy

5.4 kGy/hr, 45 kGy

1.7 kGy/hr, 45 kGy

0 kGy

5.4 kGy/hr, 45 kGy

1.7 kGy/hr, 45 kGy

0 kGy

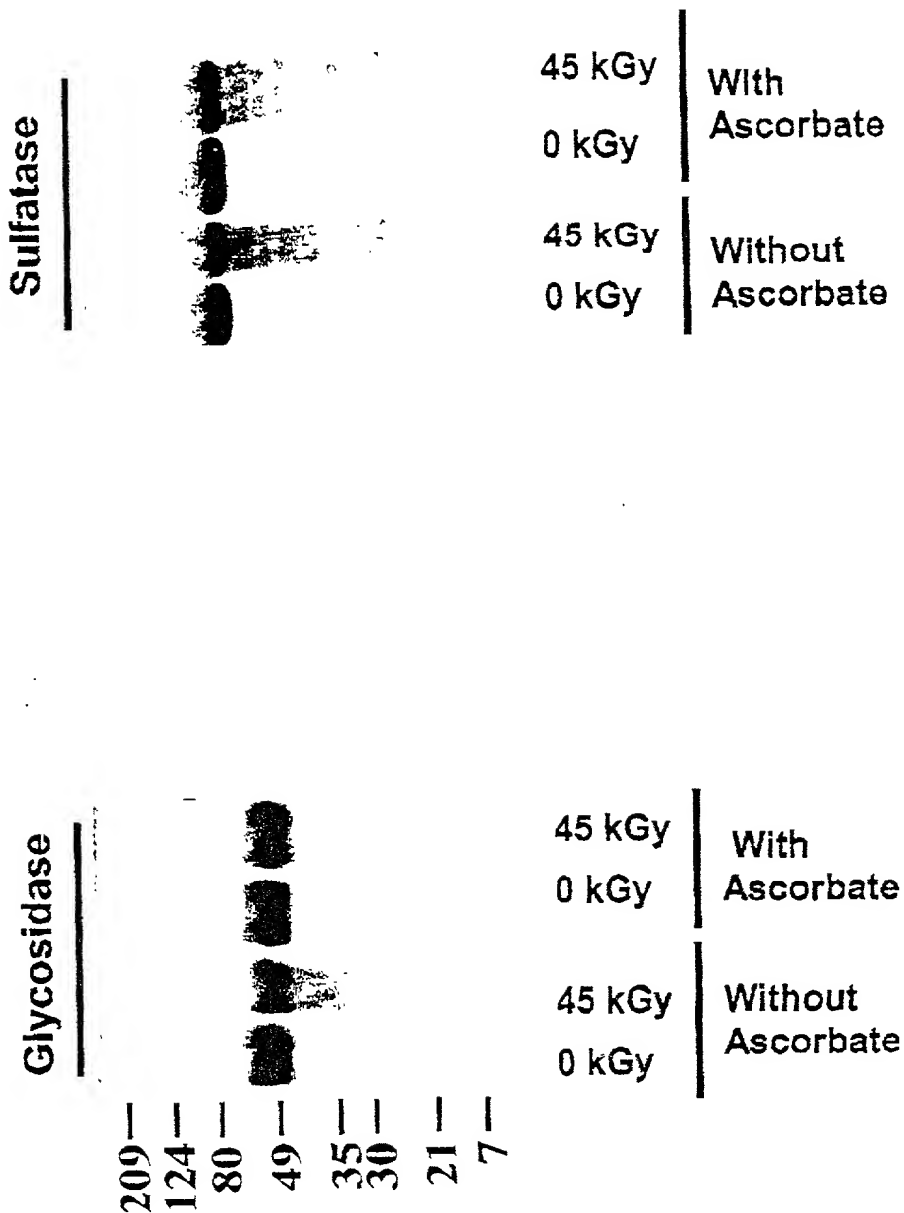
Ascorbate
and Gly-Gly

Ascorbate

46B

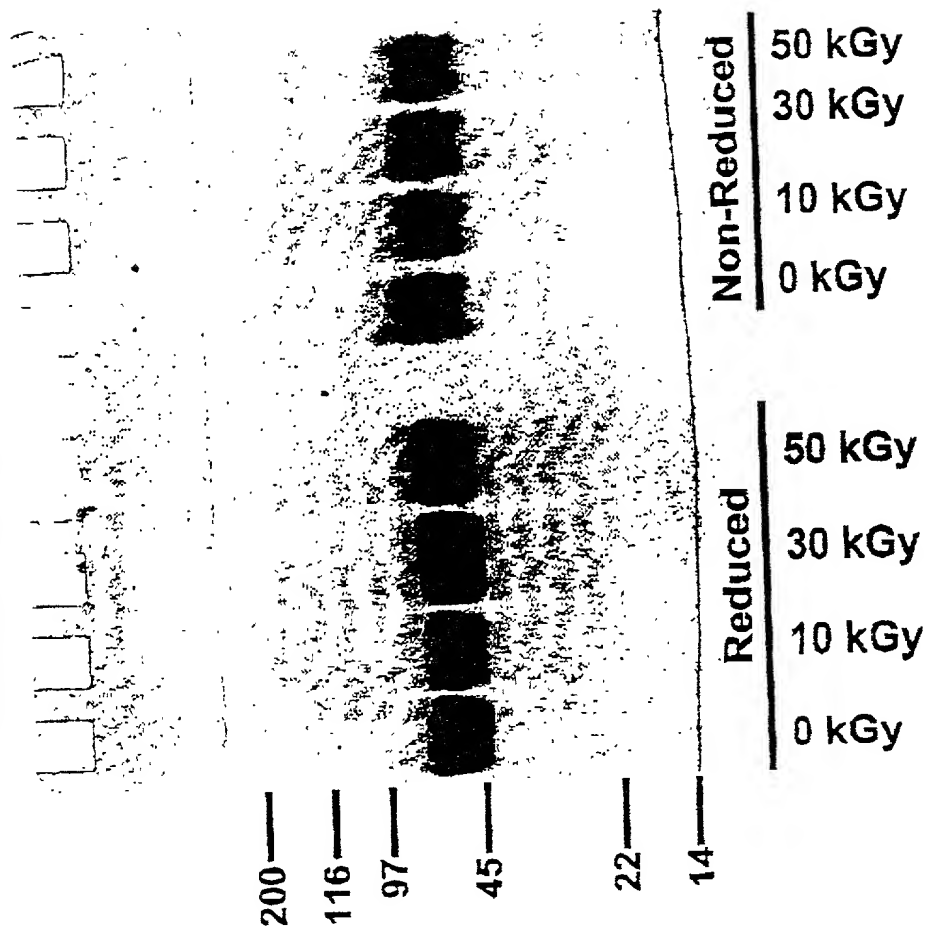


Gamma Irradiation of a Lyophilized Glycosidase and Sulfatase In the Absence and Presence of 100mM Ascorbate



Gamma Irradiation of a Lyophilized Glycosidase In the Absence of Stabilizers

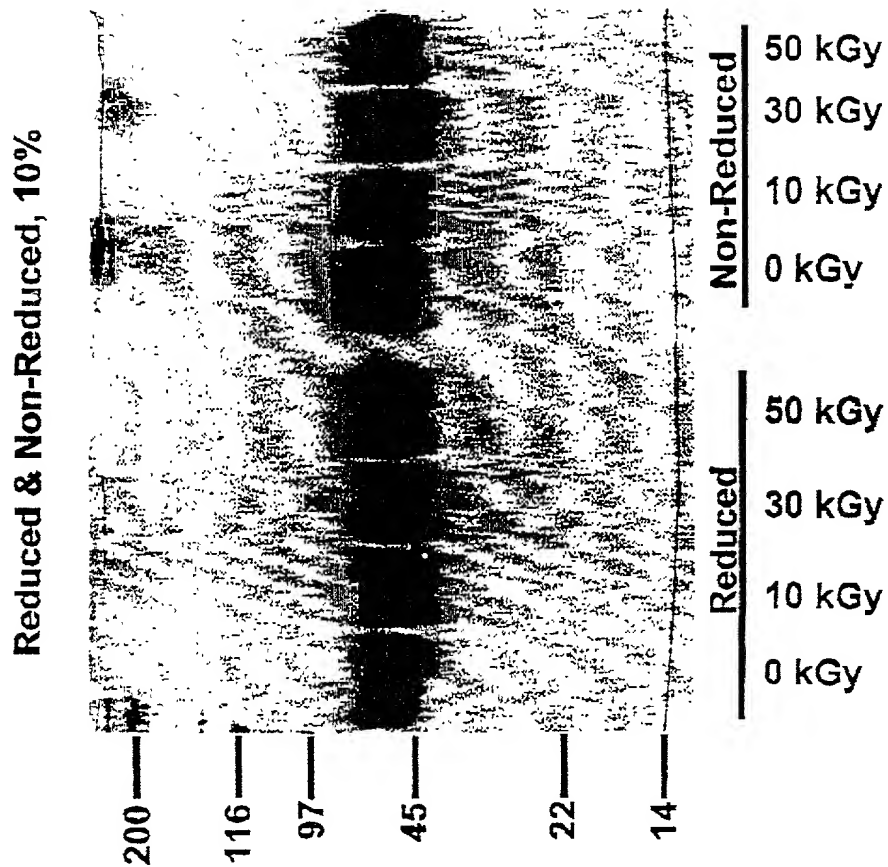
Reduced and Non-Reduced, 10%



49A



Gamma Irradiation of a Lyophilized Glycosidase In the Presence of 200mM Ascorbate and 200mM Gly-Gly



49C